

UPDATE ON OTC DENTAL PRODUCTS: HOW TO MAKE INFORMED CHOICES

Karen Baker, M.S.Pharm., Associate Professor

I. Regulation and Evaluation

- A. Federal Trade Commission (FTC)
- B. Food and Drug Administration (FDA)
- C. American Dental Association (ADA)
- D. Canadian Dental Association (CDA)
- E. Health Protection Branch of Canada

II. Information Sources for Dental Professionals

- A. ADA
 - Headquarters phone (312) 440-2500, (800) 621-8099
 - Internet: <http://www.ada.org>
 - Council on Scientific Affairs, Ext. 2840
 - Professional Product Review published quarterly at www.ada.org/goto/ppr
- B. **ADA Additional Oral Health Benefit Required for Demonstration of Superiority**
 - Manual/powered toothbrushes, floss and interdental cleaners, oral irrigators – 15% gingivitis
 - Chemotherapeutic agents to control gingivitis – 20% gingivitis
 - Fluoride-containing dentifrices – 10% improvement in caries reduction
 - Regeneration of periodontal tissues – 25% gain in periodontal attachment levels
- C. **Dental Product Comparison & Ingredients List Websites**
 - www.dentalproductshopper.com
 - www.dentalcompare.com
 - www.dentalcare.com; www.colgateprofessional.com; smartlabel.colgate-ingredients listed
 - www.dailymed.nlm.nih.gov/dailymed - best for complete ingredients and package photo
- D. **Professional Newsletters and Evidence-Based Resources**
 - "National Dental Practitioner Based Research Network"-NationalDentalPBRN.org
 - Monthly newsletter on practitioner database study results
 - Adds credibility and excitement to your practice without undue time demands
 - "Clinician's Report and Dental Hygiene Report" – www.cliniciansreport.org
 - edited by Dr. Gordon Christensen and published each month
 - paper or online subscriptions available. Cost is \$95/\$165 or \$35/\$165 (DH)
 - "Nutrition Action Health Letter" – www.cspinet.org
 - edited by Michael Jacobson – nonprofit "food police"
 - to order Fax 202.265.4954, cost is \$24/year, \$42/ 2 years for both US and CA versions
 - "Dental Advisor and Dental Advisor Plus"-www.dentaladvisor.com
 - edited by Drs. John Farah and John Powers and published 4/6 times yearly
 - "Dental Advisor" \$59/year with first year online subscription FREE
- E. **Promotional Literature/Product Ingredient Sources**
 - www.dentaldepot.com, www.dentist.net, www.dentalcare.com
 - Dental Products Report is free online and paper at www.dentalproductsreport.com
 - Reality. Product Evaluations Publications. www.realityesthetics.com
 - Dentistry Today ,free at www.dentistrytoday.com
 - Just4Teeth.com,wide assortment of mechanical and chemical products
- F. **Alternative Dental Product and Healthcare Quackery Prevention Resources**
 - Natural Medicines Comprehensive Database,800.995.8712, www.naturaldatabase.com
 - www.consumerlab.com is \$69 for 2 years and a very valuable resource
 - www.foodnews.org; www.ific.org, www.quackwatch.org, www.naturowatch.org
 - http://nccih.nih.gov, cancer.gov/about-cancer/treatment/cam
 - free sites like www.science-basedmedicine.org and www.supplement-clarity.com.

III. Chemotherapeutic Products for Home Use

Chemotherapeutic Categories

1. **General Mechanisms of Action**
 - Decrease rate of new plaque accumulation
 - Decrease or remove existing plaque
 - Suppress growth of pathogenic microflora
 - Inhibit production of virulence factors
2. **Application Method**
 - Brush on dentifrices or gels
 - Mouthwash: pre-brushing or postbrushing
 - Mouthwash: pre-procedural
 - Irrigation: supra-gingival or sub-gingival
 - Local application reservoir

CHEMICAL CATEGORIES OF SPECIFIC AGENTS AND PRODUCTS

<u>CATEGORY</u>	<u>SPECIFIC AGENTS</u>	<u>PRODUCT NAMES</u>
Anionic Surfactants	Detergents such as sodium lauryl sulfate and cocamidopropylbetaine	Pre-brushing rinses, almost all toothpastes Almost all toothpastes that foam in the mouth
Antioxidants	Ferulic acid, phloretin, ECGC, vitamin C	Periosciences rinse and toothpaste, Protandim
Bisbiquanides	Chlorhexidine *	Peridex, Periogard, ProSoL Paroex alcohol free, generics
Chelation Agents	EDTA (edathamil)	Livionex Inc. Dental Gel, Los Gatos, CA
Halogens	Chloramine-T Chlorine Dioxide Fluoride Iodine/Iodophors* Oxychlorosene Povidone-iodine	Chlorazene Oxyfresh Rinse/Paste, Clos-Sys IIRinse/Paste, etc. MFP= 14% F ⁻ , NaF= 45% F ⁻ , SnF₂= 24% F⁻ , Ora-5, iClean Mouthrinse, Kasdenol Betadine, Perimed
Metal Salts	Zinc Citrate or Zinc Chloride Tin*	TC (Aim, Close-Up, Tom's of Maine) Lavoris, Listermint, Viadent Advanced Care TP, Crest Pro-HealthTP,
Herbal Extracts	Melaleuca* Sanguinaria	Confident Paste and Rinse, Tea Tree Products, etc. AKA Bloodroot but can cause leukoplakia
Oxygenating Agents	Carbamide Peroxide Perborates Peroxides	Gly-Oxide, Proxigel, Triology Debriding Rinse Amosan Ortho-Fluor, Perimed, Peroxyl, "White Bottle" rinses S.T. 37
Phenolic Compounds	Hexylresorcinol Listerine* (thymol, Eucalyptol, Menthol, methylsalicylate) Phenol Triclosan* (Tufts Newsletter- Oct. 1998, Volume 16, (8) \$3.00)	Many generic formulations also available Cepastat, Chloraseptic, Carmex Lip Balm Mentadent-P (zinc citrate, NaF), Colgate Gum Protection (2% copolymer, NaF) Colgate Total (2% copolymer, NaF)
Quaternary Ammonium Compounds	Benzethonium Chloride Cetylpyridinium Chloride* Domiphen Bromide	Scope, Crest Toothpaste with Scope Cepacol, Crest Pro Health Viadent Rinse, BreathRx, Colgate Total Advanced ProShield, Smart Mouth Scope
Surface modifying Agents	Delmopinol* Simethicone, dimethicone	PerioShield Mouthrinse by Sunstar Butler GUM AP-24, Control Rx by Omnii

*Denotes a chemical proven to reduce gingivitis at least 20% more than brush twice daily with fluoride toothpaste

B. Dentifrices [Approximately \$1.8 Billion spent in 2015]

1. Types

ANTI-CAVITY	ANTI-GINGIVITIS	ANTI-CALCULUS	BAKING SODA	"NATURAL"
KID'S	DETOXIFYING	DESENSITIZING	DEODORIZING	WHITENING
				PROTECT ENAMEL

2. DENTIFRICE PRODUCT TABLES WITH IMPORTANT CHARACTERISTICS

a. ADA Accepted Fluoride Dentifrice Characteristics

<u>Product</u>	<u>F⁻ Compound</u>	<u>Cleaning*</u>	<u>Abrasion*</u>	<u>RDA+</u>
Aim Cavity Protection (Church&Dw)	.80 MFP	/58	M	80
A&H Dental Care Advanced Cleaning with Baking Soda (Church&Dwight)	.24 NaF	-	M	106
Aqua-Fresh Fl Protection (GSK)+++	.76 MFP	59 (3)	M	108+
Colgate Cavity Protection gel/paste+++	.76 MFP	39/(4/3)	M/L	68+
Colgate Enamel Health (Colgate)	.24 NaF	-	-	-
Colgate For Kids gel/paste (CP)+++	.243NaF	40/(4/3)	M/	77+
Crest Pro-Health "For Me" paste	.243NaF			
Crest Cavity Protection paste/gel (P&G)+++	.243 NaF	69/70(4)	M	115/96+
Crest Kids Sparkle Fun (P&G)	.243 NaF	-	-	80
Enamelon TP with ACP (Premier)	.45 SnF	-	-	39
Shane AloeSense (Aloesense.com)	.243 NaF	-	-	90
Tom's of Maine Natural BS Fl TP	.80 MFP	-	-	49
Tom's of Maine Natural Fluoride Spearmint or Wintermint (Colgate)	.80 MFP	59/(4)		93+
Tom's of Maine Natural Fluoride for Children SillyStrawberry,OutrageousOM	.76 MFP	-	M	57

*Consumer Reports, 9/1992 or 8/1998

~Journal of Dentistry 20:283-286, 1992

#Available Rx only, not ADA accepted

~Reported by Manufacturer

+ADA Council on Dental Therapeutics, May 1993

++Oral Health Research Institute, Indiana Univ. RDA 92-69

+++ CDA Accepted

() Cleaning score in Consumer Reports 8/1998 on 1-5 scale

PATIENT POINTS:

1. NaF is the best fluoride compound for root caries risk and recession patients
2. SnF 0.4% is really about 970ppm which is similar to other OTC fluoride dentifrices
3. NaF is 45% fluoride, MFP is 14% fluoride, SnF is 24% fluoride

b. Prescription Strength Fluoride Dentifrice Characteristics

<u>Product</u>	<u>F⁻ Compound</u>	<u>Additional Ingredients</u>	<u>RDA+</u>
ClinPro 5000 1.1% NaF (3M ESPE)	1.1% NaF	5% Novamin	68
Cypress SF 5000 Plus (Cypress)	1.1% NaF	-	-
Denta5000 Plus (Rising Pharma)	1.1% NaF	Pyro and SLS	80
Fluoridex (Discus)#	1.1% NaF	May have KNO3	-
FluoriMax 5000 (Elevate Dental Care)	1.1% NaF	10% Xylitol	-
Just Right 5000 Metered Dose	1.1% NaF	.25g per pump	
Prevident 5000 Plus (CP)#	1.1% NaF	-	80
Prevident Dry Mouth (CP)#	1.1% NaF	No SLS	110
Prevident Booster (CP)#	1.1% NaF	Penetrating Formula	110
Prevident Sensitive (CP)#	1.1% NaF	5% KNO3	90
Pro-Dentx (Pro-Dentec)#	1.1% NaF	-	90
Topex Renew (Sultan Healthcare)#	1.1% NaF	5% Novamin	109

*Consumer Reports, 9/1992 or 8/1998

#Available Rx only, not ADA accepted

+ADA Council on Dental Therapeutics, May 1993

PATIENT POINTS:

1. 5000ppm NaF remineralizes 25-35% better than 1000-1100ppm NaF
2. ClinPro and Renew haven't been evaluated in human clinical trials as of 7/8/2010
3. Prevident Booster formula is primarily to increase compliance
4. 5000ppm NaF does not effectively REVERSE white spot lesions

c. ANTI-PLAQUE AND GINGIVITIS DENTIFRICES (*ADA Accepted for Plaque/Gingivitis)

<u>Product*</u>	<u>Cleaning</u>	<u>F-</u>	<u>RDA</u>	<u>Other Ingredients</u>
Act Dry Mouth (Chattem)	-	NaF	-	Optaflow technology, xylitol, licorice root extract
AP-24 (Nu-Skin)	-	MFP	-	Dimethicone, surfactants Poloxamer 407, 338
Biotene paste and gel (GSK)	-	MFP	78	Glucose oxidase, lactoperoxide, CMPB
Biotene PBF paste (GSK)	-	MFP	78	Calcium lactate, mucinase, dextranase, CMPB
Close-Up Anti-Plaque (C&D)	62	SnF	85	Stannous pyrophosphate, zinc citrate
CloSys II (Rowpar)	-	-	53	Stabilized chloride dioxide 0.1%, no SLS
Colgate Total SF ADeepClean	-	SnF	70	SnF, zinc phosphate, sodium pyrophosphate, SLS
Colgate Total SF AFreshPlus	-	SnF		SnF, zinc phosphate, sodium pyrophosphate, SLS
Colgate Total SF Whitening	-	SnF		SnF, zinc phosphate, sodium pyrophosphate, SLS
Crest ProHealth (PG)	-	SnF	155	Stannous Fluorite, Sodium hexametaphosphate
Crest ProHealth EnamelShield	-	SnF	144	Stannous Fluorite, Sodium hexametaphosphate
Crest Pro Health for Life	-	SnF	140	Stannous Fluorite, Sodium hexametaphosphate
Listerine EC paste/gel (J&J)	60/(4)	MFP	85	Essential oil ingredients as in the rinse
Livionex Dental Gel (Livionex)	-	-	-	“Activated” edathamil (EDTA) to chelate calcium
Oral Defense (BioGlobe Tech)	-	NaF	-	Cetylpyridinium Cl, no SLS
Oxyfresh (Oxyfresh USA)	-	-	45	Stabilized chloride dioxide
Parodontax Toothpaste (GSK)	-	SnF		Stannous Fl, Glycerin, hydrated silica, SLS, CMPB
Plaque HD Disclosing (TJA)	-	NaF	-	Pyros, SLS, Annatto extract, EDTA, FD&C Blue 1
SmartMouth Advanced	-	MFP	-	Zinc Chloride 2% , .81% MFP
Clinical Formula (Triumph)				
Tom’s of Maine Antigingivitis	-	-	68	Zinc citrate 2%, xylitol, baking soda

* Colgate Total and Crest ProHealth are ADA accepted for plaque/gingivitis reduction beyond regular fluoride toothpaste
 PATIENT POINTS

1. Colgate Total Whole Mouth Health now contains Stannous fluoride and zinc phosphate-not ADA accepted.
2. Essential oils or zinc are about 16-19% effective at reducing gingivitis so are not ADA accepted.
3. Chlorine Dioxide toothpaste is NOT effective at reducing gingivitis but reduce oral malodor
4. Crest Pro-Health reduces mild/moderate gingivitis about 25% compared to regular fluoride toothpaste
5. Biotene toothpastes do not have specific anti-gingivitis ingredients other than fluoride.
6. Activated edathamil (EDTA) is a common food additive which is safe and may inhibit plaque formation.

d. BAKING SODA DENTIFRICES

<u>Product</u>	<u>F-</u>	<u>RDA*</u>	<u>% Baking++ Soda</u>	<u>% Hydrogen++ Peroxide</u>	<u>Cleaning+</u>
A&H Bright and Strong Truly Radiant (C&D)	NaF			CaPer/Sulfate	
A&H Clean and Fresh Truly Radiant (C&D)	MFP				
A&H Complete Care Paste (Church & Dwight)	NaF	57	30	-	24
A&H Rejuvenating Truly Radiant (C&D)	NaF				
Aquafresh Baking Soda (GSK)	MFP	65	.5	-	(3)
Arm & Hammer Baking Soda (Church & Dwight)	-	7	100	-	-
A&H Dental Care Paste (Church & Dwight)	NaF	35	65	-	28(2)
Aim Baking Soda Gel (Church & Dwight)	MFP	-	.5	-	-
Close-Up Baking Soda Paste (Church & Dwight)	MFP	80++	.5	-	-
Colgate Baking Soda Paste (Colgate)**	NaF	120	25	-	51
Colgate TC Baking Soda and Peroxide Paste (Colgate)	NaF	92	12	0.50CaPeroxide	(4)
Mentadent Baking Soda and HP Combo (Church & Dwight)	NaF	118	5	.75	(4)
Pepsodent with Baking Soda Paste (Church & Dwight)	NaF	80++	5	-	-
Peroxicare Deep Clean (Church & Dwight)	NaF	52	52	0.75NaCarbPerox	25
Sensodyne Baking Soda (GSK)	NaF	67	-	-	(3)
Tom’s of Maine BS Peppermint/Gingermint (Colgate)	MFP	68	5	-	-

*Indiana Oral Health Research Institute, 1999

+Consumer Reports 9/98, ++Per Manufacturer, **ADA Accepted for Caries Reduction

PATIENT POINTS

1. Higher baking soda content leads to lower cleaning scores
2. Baking Soda and Hydrogen Peroxide have no therapeutic effect singly or in combination

e. NATURAL DENTIFRICES

<u>Product/Manufacturer</u>	<u>Claims</u>	<u>“Active Ingredients”</u>
Auomere (www.auomere.com)	Invigorates/purifies	Neem, Peelu, 24 herbal extracts
Colgate Hydris Dry Mouth Toothpaste	Locks in a hydrated feeling	Hydrogenated coconut oil
DentiCare Tooth Polish (Melaleuca, Inc.)	Benefits bleeding gums	Melaleuca, propolis, myrrh
Dentaforce (Bioforce)	Astringent/stimulant	Echinacea, rosemary, essential oils
Eco-Dent (Eco-Dent 888.Eco.Dent)	Hardens enamel w/o F	BS, tartaric acid, CaCO ₃ , myrrh
Cool Mint (Nature’s Gate)	Antiseptic/ “free” calcium	Sage, vitamin C, Calcium Carrot Pwd.
Healthy Teeth & Gums toothpaste (www.thenaturaldentist.com)	Prevent cavities/fight gingivitis	MFP, aloe vera, echinacea, goldenseal, calendula,propolis,grapefruit seed extr.
Homeodent (Boiron-Borneman)	No-mint	Calendula, plantain, horseradish, witchhazel
Jason Toothpaste (www.jason-natural.com) some with Fl-	Best tasting natural toothpaste!	CoQ10, Aloe Vera, Sea Salt, Melaleuca,
Kiss My Face (KMF)	Gum support/perio protection	Perilla Seed Extract
MCT Oil Toothpaste (The Dirt)	Pure and natural	NaMFP,aloe vera,micronized silica
MouthFx (www.mouthfx.com)	Blows others out of the water	Coconut oil, bentonite clay, theobromin
Nutribiotic Dental Gel (www.nutribiotic.com/dentalgel)	97% effective in 41 countries	100% natural essential oils
Parodontax-F (www.parodontax.de) GSK	Supports teeth and gums, No fluoride which is toxic	Grapefruit Seed Extract, Zinc Citrate, sanguinaria, aloe vera, stevia
Peelu (Peelu Products)	Soothing herbs/mineral plus Fl-	BS,Rhatany, chamomile,myrrh,fluoride
Propolis TP (Beehive Botanicals)	Miswak/Siwak chewing stick	Peelu fiber, natural sorbo fruit juice
Tea Tree Oil TP (Desert Essence)	Protects hive, benefits mankind	Propolis, xylitol, flavoring oils
Tea Tree TP (Thursday Plantation)	Especially good for gingivitis/perio	Melaleuca, propolis, ginger
The Dirt Natural Toothpowder	Healthy gums, decrease tartar	0.4% melaleuca, chlorophyllin-copper
Tom’s of Maine (Colgate)	Paleo friendly and xylitol free	Bentonite clay,baking soda, myrrh gum
Tooth and Gum Paste (DHC)	No dyes, preservatives, sweetners	Some with F-, xylitol, many formulas
	No SLS, “natural F source” (tea)	Fl-,Echinacea, green tea, essential oils

PATIENT POINTS: 1. Non-Fl: Denticare, Dentaforce, Propolis, Tea Tree Toothpaste

2. Fl: Denticare, Healthy Teeth&Gums , Jason HealthyMouth, Tom’s of Maine Fl-, Tooth&Gum Paste

f. TARTAR CONTROL DENTIFRICES

<u>Product</u>	<u>F</u>	<u>Cleaning+</u>	<u>RDA*</u>	<u>Other Ingredients</u>
Aim TC (Church&Dwight)	.80 MFP	-	108	Zinc citrate 0.5%
Aquafresh TC (GSK)	.24 NaF	(4)	124	Tetra NA pyrophosphate 3.3%
A & H TC Toothpaste (Church&Dwight)	.24 NaF	-	34	Napyrophosphate, Naphosphate
A&H TC Gel (Church&Dwight)	.24 NaF	-	71	Napyrophosphates
Close-Up TC Paste (Church&Dwight)	.76 MFP	62	98	Zinc citrate 0.5%
Close-Up TC Gel (Church&Dwight)	.76 MFP	63	-	NaCl, zinc citrate 0.5%
Colgate TC Gel (CP)	.24 NaF	74	87	3.3% tetraNapyrophosphate, PVM/MA
Colgate TC Paste (CP)	.24 NaF	62	165	3.3% tetraNapyrophosphate, PVM/MA
Colgate TC Gel/Paste MCF (CP)	.24 NaF	-	87/113	3.3% tetraNapyrophosphate, PVM/MA
Colgate TC Micro Cleansing (CP)	.24 NaF	(4)	112	3.3% tetraNapyrophosphate, PVM/MA
Kiss My Face TC with Zinc Citrate	-	-	-	Zinc citrate, aloe vera, lemon flavored
Listerine EC TC Gel/Paste (J&J)	.76 MFP	(4)	90	Zinc citrate trihydrate, essential oils
Natural White TC (Natural White)	.24 NaF	-	113	TetraK pyrophosphate
Pepsodent Complete Care(Ch&Dwight)	.76MFP	-	-	Zinc citrate, silica
Rembrandt TC Paste (J&J)	.80 MFP	-	55	"Citroxain" = alumina, papain, citric acid
Sensodyne TC/Plus Whitening (GSK)	.24 NaF	-	100	KNO ₃ , tetra Kpyrophosphate, silica
Tom’s of Maine TC&Whitening (Colgate)	-	-	90	Zinc citrate, xylitol, hydrated silica
Ultra-Brite All in One (C-P)	.24 NaF	-	-	Pyrophosphates, no alumina

PATIENT POINTS: 1. Pyrophosphates are associated with dentinal sensitivity and soft tissue lesions.

2. Sodium Hexametaphosphate produces adverse effects equivalent to standard pyrophosphates.

3. Switch to zinc salts to get calculus reduction without sensitivity and soft tissue lesions.

g. DESENSITIZING DENTIFRICES

<u>Product</u>	<u>F⁻</u>	<u>Densensitizer</u>	<u>Cleaning+</u>	<u>RDA++</u>
AquaFresh Sensitive (GSK)*	NaF	5% KNO ₃	(3)	91
A&H Sensitive Teeth and Gums (C&D)	NaF	5% KNO ₃	50/(2)	54
Biotene Sensitive Toothpaste (Laclede)	MFP	5% KNO ₃	-	55
ClinPro 5000 1.1% NaF Dentifrice with Calcium and Phosphate	NaF	Ca and Phos	-	68
Colgate Enamel Health Sensitivity Relief (CP)	NaF	5% KNO ₃	-	-
Colgate Sensitive Pro Relief 1500ppm (CP)	NaF	5% KNO ₃	-	62
Crest Pro-Health (P&G)	SnF	SnF	-	100
Crest Sensi Relief (P&G)	NaF	5% KNO ₃	(3)	107
Crest Sensi Repair and Prevent (P&G)	SnF	SnF	-	-
Denclude Desensitizing Dental Cream with Sensistat (Ortek)	-	Sensistat	-	-
Dr. Collins Restore with Novamin	-	Novamin	-	-
Enamelon Preventive Treatment Gel (Premier)	.45SnF	Ca and Phos	-	39
Kiss My Face Sensitive Fluoride-Free with Aloe (KMF)	-	5% KNO ₃	-	-
Level OralCare Sensitivity Herbal with Xylitol (Level Oral Care)	.76MFP	5% KNO ₃	-	-
Orajel Sensitive (Del)*	1%MFP	5% KNO ₃	-	-
Prevident Sensitive (P&G)	NaF	5% KNO ₃	-	90
Sensodyne Baking Soda (GSK)	NaF	5% KNO ₃	(3)	55
Sensodyne Cavity Prevention (GSK)*	MFP	5% KNO ₃	(3)	89
Sensodyne Complete Protection (GSK)	SnF	-	-	-
Sensodyne Fresh Mint* (GSK)	MFP	5% KNO ₃	-	89
Sensodyne Cool Gel (GSK)	NaF	5% KNO ₃	-	92
Sensodyne Original Flavor (GSK)	MFP	5% KNO ₃	80	100
Sensodyne Pronamel (GSK)	NaF	5% KNO ₃	-	39
Sensodyne Repair and Protect (GSK)	SnF	-	-	-
Tom's of Maine Sensitive Teeth Natural Toothpaste (Colgate)	-	5% KNO ₃	-	68
Tom's of Maine Rapid Relief Sensitive (Colgate)	-	Pro-Argin	-	-
Topol Plus Sensitive Teeth (Dep)	MFP	5% KNO ₃	-	-

- PATIENT POINTS:**
1. Potassium Nitrate and SnF are most effective for OTC twice daily use.
 2. Patient should consult dentist after 4 weeks of twice daily use with no positive effects.
 3. Abrasivity should be selected at an RDA of 120 or below

h. WHITENING" DENTIFRICES (# ADA Accepted for Extrinsic Stain Removal)

<u>Product</u>	<u>F⁻</u>	<u>Cleaning</u>	<u>Abrasion+</u>	<u>RDA</u>	<u>"Whitening Ingredients"</u>
Aquafresh Whitening TC (GSK) #	NaF	(4)	M	113	Na tripolyphosphate
Aquafresh Iso-active Whitening	NaF				Na tripolyphosphate, Isopentane
A&H Adv. White Extreme	NaF	(3)	L	106	TetraNapyrophos,BS Napercarbamate
A&H Adv White Breath Freshening	NaF	-	-	-	BS, silica, cal sulfate, cal peroxide
Close-Up Paste/Gel (Church&Dw)	MFP	85/72(4)	H	110/80	Silica, titanium dioxide in Clear
Colgate Essentials Whitening-Char	MFP				Silica,activated charcoal,4 detergents
Colgate Essentials Whitening-Coco	NaF				Silica,SLS,coconut oil,pyrophosphate
Colgate Fresh Confidence Whitening	NaF	75	M	124	TetraNa pyrophosphate,Ultra mint
Colgate Sensitive Plus Whitening	SnF	51		120	Micronized Silica
Colgate Optic White Anticavity	MFP	-	-	-	Hydrogen Peroxide,pyrophosphates
Colgate Sparkling White BS, Per	MFP	-	-	-	Silica, BS, pentaNa triphos, pyropho
Colgate Sparkling White TC #	NaF	69	-	190	Silica, pentaNa triphosphate, pyropho
Colgate Whitening BS, Per, TC	MFP	(5)	M	145	BS, alumoxide, pyrophos, td, Caperox
Crest Extra Whitening (P&G)	NaF	-	M	130	Silica,
Crest Multicare Whitening (P&G) #	NaF	62	M	144	Silica 31%, BS 1.5%, pyrophosphate
Crest Pro-Health Whitening (P&G)	SnF			155	Silica,sodium hexametaphosphate
Crest Pro-Health HD 2 step (P&G)	SnF				SnF followed by hydrogen peroxide
Crest 3D White Therapy-Charcoal	NaF			205	Silica, pyrophosphate,SLS,Charcoal
Crest 3D White Therapy-Coconut	NaF				Silica,pyrophos,SLS,Coconut Oil
Crest Whitening Plus Scope (P&G)	NaF	52	M	125	Scope MW ingredients,pyrophosphate
Gleem (P&G)	NaF	79	M	118++	Silica, triNaphosphate, titanium diox

Luster Premium Deep Stain Eraser	NaF	-	-	-	Silica, Urea peroxide, corn starch
Natural White (Natural White)	-	-	M	101++	Silica, glycerin, titanium dioxide
Pearl Drops BS Paste (C&D)	NaF	-	-	-	TetraK&Na pyrophosphates, BS, td
Pearl Drops Paste (C&D)	NaF	74		195	Silica
Pearl Drops Toothpolish (C&D)	NaF	(4)	H	227++	Silica, AlHydroxide, triNaphosphate
Pepsodent F ⁻ (Church&Dwight)	MFP	58	M	150	Silica
Plus White (CCA)	MFP	-	M	94++	TriNaphosphate, monoNaphosphate
Rembrandt Plus # (J&J)	MFP	53(3)	L	55++	Citroxain(papin, alumina, NaCitrate)Carbamide peroxide
Rembrandt Plus Premium Whit. Gel with Peroxide (J&J)	MFP	-	L	70+	Carbamide peroxide < 3% citroxain
Rembrandt Whitening Cankersore	NaF	-	L	55++	Citroxain, hydrated silica
Rembrandt Intense Stain Removal	NaF	-	-	94	Dicalcium phosphate, silica, alumina
Sensodyne Extra Whitening (Block)	MFP	-	-	150	KNO ₃ , calcium peroxide
Supersmile (Robell Research)	MFP	-	L	62+	Calcium peroxide, titanium diox, BS
Topol Plus BS (Topol-Dep)	MFP	-	-	-	Silica, BS, diNaphosphate, titan diox
Topol Smoker's Fluoride Gel (Dep)	MFP	82	H	207++	Silica, Zirconium silicate, titandiox
Topol Smoker's Toothpaste/Fl ⁻ (Dep)	MFP	76	H	227++	Silica, Zirc. silicate, titan. diox., tetra NaPyrophosphate
Marvis Whitening Toothpaste	MFP	-	-	-	TetraNaPyro,SLS,xylitol,ITALIAN
Ultra-Brite BS (C-P)	MFP	-	M	-	Silica, BS, alumina, titanium dioxide
Ultra-Brite BS & Peroxide (C-P)	MFP	(3)	M	-	Silica, BS, prop glycol, Caperoxide
Ultra-Brite Paste/Gel (C-P)	MFP	86/72(5)	M/M	133++	Silica, alumina, titan. dioxide, pyro
Ultra-Brite Advanced Whitening	MFP	-	M	260	

*Consumer Reports 9/92 or 8/98 Journal of Dentistry 20:283-286, 1992, +Reported by the manufacturer 5/95 (L=low, M=moderate, H=high), ++Oral Health Research Institute, Indiana University, RDA 92-69, # = ADA ACCEPTED FOR REMOVAL OF SURFACE STAIN

- PATIENT POINTS:**
1. **Toothpastes cannot effectively bleach teeth and can only remove extrinsic stain.**
 2. **Cleaning ability does not necessarily correspond to abrasivity.**
 3. **Chronic exposure to peroxides should be avoided in tobacco users.**
 4. **FDA recommends RDA limit of 200 while ADA recommends limit of 250.**
 5. **FDA recommends RDA limit of 200 while ADA recommends limit of 250.**

a. Options for Whitening is Based on Patient Preference and Tolerance

- ❖ **Least effective are whitening toothpastes because they only polish off stained pellicle**
- ❖ **Next most effective is OTC Whitestrips with the most effective being Crest“Advanced”**
- ❖ **At-Home or In-Office Bleaching Using Custom Trays are Equally Effective**
- ❖ **At-Home Bleaching leads to longer shade maintenance than In-Office Bleaching**

IV. SALIVA ENHANCERS

A. NeutraSal (OraPharma) and SalivaMax (Forward Science) –supersaturated calcium phosphate as a powder packet for immediate rinsing.

B. Novamin (calcium sodium phosphosilicate) by NovaMin Technology Inc. of Alachua, FL.

Calcium Sodium-phosphosilicate (Novamin)

A synthetic mineral composed of calcium, sodium, phosphorous and silica, all elements naturally occurring in the body. Silica (glass) containing Ca and PO is the driving mechanism that binds to the tooth surface

1. Omnii Oravive Tooth Revitalizing Paste (Oravive)
2. DenShield Tooth Sensitivity Therapy (Novamin)
3. Butler NuCare Tooth Root Conditioner (Butler)
4. SootheRx Sensitivity Therapy (Omnii)
5. Dr. Collins Restore Toothpaste for Home Use
6. Topex Renew by Sultan is Novamin plus NaF 5000ppm

C. Tri-Calcium Phosphate – ClinPro with NaF 5000ppm – 3M Espe

D. Recaldent (casein phosphopeptide-amorphous calcium phosphate)

Casein phosphopeptide and amorphous calcium phosphate (CPP-ACP)

Casein phosphopeptide is a milk protein peptide that is bound to amorphous calcium phosphate

The milk derived peptide containing amorphous Ca and PO is the driving mechanism that binds to the tooth surface.

5. Sugarless gum – Trident White and Trident for Kids Berry
6. MI paste and MI PastePlus with 5:3:1 mineralization ratio by GC America
7. MI Paste One – dentifrice with RDA of 64 for one step cleaning and mineralization

E. Soluble Calcium Sulfate

8. Arm & Hammer Enamel Care Toothpaste (Church and Dwight)

F. Amorphous Calcium Phosphate (ACP)

ACP is inorganic amorphous calcium phosphate, made by combining soluble salts of calcium and phosphorous

1. Relief ACP Oral Care Gel by Discus Dental
 - NaF 0.22%
 - Potassium Nitrate 5%
 - Amorphous Calcium Phosphate 0.375%

G. Arginine Bicarbonate and Calcium Carbonate (Sensistat) – Now Pro-Argin (Colgate)

Arginine bicarbonate is an amino acid complex found in saliva that is bound to calcium carbonate

1. Proclude (Ortek) 2. Denclude (Ortek) 3. Tom's of Maine Rapid Relief Sensitive Toothpaste

V. MOUTHWASHES USED FOR COSMETIC AND THERAPEUTIC EFFECTS

A. PROPERTIES OF SELECTED OVER-THE-COUNTER MOUTHWASHES

<u>Product (Manufacturer)</u>	<u>Alcohol (%)</u>	<u>PH</u>	<u>Active Ingredients</u>
Advanced Breath Care (Arm&Hammer)	15	9.1	Baking Soda, Zince Citrate, Cetylpyridinium Cl
Biotene (Laclede)	0	6.5	Glucose oxidase, lactoperoxidase, lysozyme
Cepacol (SKB)+++	14.5	6.0	Cetylpyridinium chloride 0.05% (not bioavailable)
Colgate Hydris Rinse for Dry Mouth	0	6.0	Glycerin, cellulose,PG, CPC, Sorbitol, twice daily
Crest Pro-Health Complete (P&G)	0	6.0	NaF-.0219%, CPC for twice daily use
Crest Pro-Health Mouthrinse (P&G)	0	4.7	Cetylpyridinium chloride 0.07%
Crest Pro-Health Advanced Tartar Protect	8	6.0	NaF 0.02%, two pyrophosphates for tartar control
Colgate Total Advanced Gum Health	0	4.7	Cetylpyridinium chloride 0.075%
Crest Pro-Health Enamel Shield (P&G)	0	6.4	Sodium Fluoride 0.02% for 10ml twice daily use
Crest 3D White Multicare Whitening Rinse	0	5.4	H2O2, sodium hexametaphosphate
Listerine Antiseptic Mouthrinse (J&J)	21.6	4.2	Four essential oils in a hydroalcoholic rinse
Listerine Healthy White Gentle (J&J)	14.0	6.0	NaF 0.02%, pyrophosphates,
Listerine Healthy White Restoring (J&J)	10.5	4.2	NaF 0.0221, hydrogen peroxide 2%, castor oil
Listerine Healthy White Vibrant (J&J)	8.0	4.4	NaF 0.02%, hydrogen peroxide 2%
Listerine Nightly Reset Mouthrinse (J&J)	0	6.0	NaF 0.02%, xylitol

Listerine Sensitivity Mouthrinse (J&J)	0	6.0	Dipotassium oxalate monohydrate
Listerine Total Care Anticavity Rinse(J&J)	21.6	3.2	NaF 0.0221% for 10ml 2x daily use, 4 essential oils
Listerine Total Care Stain Remover (J&J)	21.6	6.0	NaF 0.0221% for 10ml 2x daily use,2% HP, 4 EOs
Listerine Zero Less Intense (J&J)	0	4.3	Sodium lauryl sulfate, benzoic acid,sorbitol
Natural Dentist Anti-Gingivitis	0	3.3	Peppermint,sage,aloe vera, xylitol
Natural Dentist Anti-Cavity	0	7.0	Sodium Fluoride 0.05%, aloe vera, xylitol
Natural Dentist Whitening/Gingivitis	0	6.0	Peppermint,sage,citric acid,betaine
Oral Max Oral Rinse (Novus Natural)	0	3.0	Natural tannins from plant polyphenols
Peroxyl (Colgate)	0	3.7	Hydrogen peroxide 1.5%
Plaque HD Remineralizing (TJA)	0	8.4	BS,,zinc citrate,,xylitol,,melaleuca, aloe vera
Rembrandt Premium Whitening Plus (J&J)	0	4.0	.05% NaF, H ₂ O ₂ , castor oil, glycerin for once daily
Rembrandt Whitening with Fluoride (J&J)	0	6.4	0.02% NaF, H ₂ O ₂ , Castor oil for twice daily
Scope Outlast Long Lasting (P&G)	13	6.0	Concentrated flavoring oils, CPC, benzoic acid
Scope with Baking Soda (P&G)	9.9	8.4	Baking Soda, cetylpyridium chloride, domiphen br
Scope Sparkle Mouthrinse (P&G)	0	5.0	Hydrogen Peroxide, sodium hexametaphosphate
SuperSmile (Robell Res)	0	8.2	NaMFP, BS, pyrophosphates, calcium peroxide
Targon (Block)	6	5.5	Castor oil, detergents
Therasol (Oratec)	8	5.5	0.3% C31G, NaF 0.02%, glycerin
Tom's of Maine Wicked Fresh (Colgate)	0	3.1	Aloe vera, peppermint oil, zinc chloride
Tom's of Maine Natural Cleansing(Colgate)	0	2.7	Vitamin C, aloe vera, glycerin, witch hazel
Tooth and Gum Tonic (Dental Herb Co.)	0	4.7	Oils of peppermint,red thyme,cinnamon,eucalyptus

- PATIENT POINTS:
1. Listerine must say “Antiseptic” on the yellow banner in order to significantly reduce gingivitis.
 2. Mouthwash containing peroxide cannot significantly whiten vital teeth.
 3. Breath freshening effects of high concentration flavoring oils last about 1 hour.
 4. Effective oral malodor agents are zinc salts, chlorine dioxide & antimicrobial essential oils.
 5. Many fluoride rinses now contain 0.02% NaF to be used twice daily instead of 0.05% once daily.

B. PROPERTIES OF “THERAPEUTIC” MOUTHWASH PRODUCTS

<u>Product</u>	<u>Plaque Reduction</u>	<u>Toxicity</u>	<u>Alcohol</u>	<u>PH</u>	<u>Substantivity</u>
Chlorhexidine (Peridex, Periogard, generics))	High	Low	11.6%	5.6	High
Delmopinol (PerioShield,ButlerGUM.)	Moderate	Low	0%	5.7	Mod
Phenolics (Listerine gold/blue or green, TC)	Moderate	Low	26.9%/21.6%	4.4	Low
Sanguinarine (Viadent Original)	Low-moderate	Low	11.5%	4.5	Low
Quat. Ammon. Comp.++ (Scope/Cepacol, Viadent Advanced Care, Crest Pro Health)	Low	Low	18%/14%	6.5/6.0	Low
Oxygenating Agents (H ₂ O ₂ /chlorine dioxide)	Low-moderate	Low	0%	6.0	Low-Mod
Pre-brushing (Plax/New Plax)	Low	Unsure	0%	2.7/8.4	Low
	Low	low	7.5%8.5%	8.2	Low

C. THERAPEUTIC MOUTHRINSE: FLUORIDE

TOPICAL/HOME-USE RINSES

Nonprescription

Generally 0.05% NaF designed for 10ml once daily use which exposes teeth to 2.23mg F- per day

Act Restoring-11% alcohol in icy cool mint, cinnamon, vanilla mint, icy spearmint by Chattem

Act for Kids Fluoride Anti-Cavity Treatment for Kids-BB

Act Anti-Cavity ETOH-free mint or cinnamon for adults
Fluorigard Anti-Cavity Dental Rinse, Colgate-Palmolive Co.

Oral-B Rinse Therapy Anti-Cavity Treatment, Oral-B Lab
Fluorinse by Oral-B

NaFrinse Acidulated Oral Rinse 0.05%, Colgate Oral
Pharmaceuticals

Prescription

Generally 0.2% NaF designed for 10ml once weekly use which exposes teeth to about 9mg F- per day

NaFrinse Acidulated Oral Rinse and Systemic Supplement,
Orachem Pharmaceuticals

NaFrinse, 0.05%, Orachem Pharmaceuticals

NaFrinse, 0.2%, Medical Products Laboratories, Oral
Pharmaceuticals Div.

Phos-Flur® Oral Rinse Supplement, Cherry, Cinnamon,
Grape, Wintergreen, Colgate-Hoyt Laboratories, Div. Of
Colgate-Palmolive Co.

PreviDent Dental Rinse, 0.2% Colgate Oral Pharmaceuticals

COCHRANE LIBRARY REVIEW 2012

“Fluoride mouthrinses for preventing dental caries in children and adolescents”

Regular supervised use of fluoride mouthrinses by children would reduce their tooth decay, even if they drink fluoridated water and use fluoridated toothpaste.

Fluoride is a mineral that prevents tooth decay (dental caries). Since widespread use of fluoride toothpastes and water fluoridation, the value of additional fluoride has been questioned. Fluoride mouthrinse is a concentrated solution that needs to be used regularly to have an effect. The review of trials found that regular use of fluoride mouthrinse reduces tooth decay in children, regardless of other fluoride sources. One in two children with high levels of tooth decay (and one in 16 with the lowest levels) would have less decay. However, more research is needed on adverse effects and acceptability of mouthrinses.

D. Therapeutic Mouthrinses: Anti-Plaque/Anti-Gingivitis

- i. Efficacy of Crest ProHealth Mouthrinse for Gingivitis Reduction
- ii. Oxyfresh (Oxyfresh USA) – toothpaste and mouthwash for halitosis
CloSys II mouthrinse and Closys II toothpaste (Rowpar Pharmaceuticals)
ProxiPure (Dentist Preferred Inc., 1.800.997.7694) – contains chlorophyll
Ingredients: stabilized chlorine dioxide (Purogene) < pH = 8.4-9.2
Smart Mouth Advanced Clinical Formula contains CPC 0.05% and is promoted for Maximum Plaque and Gingivitis Protection along with breath odor reduction.
Smart Mouth Original Formula contains sodium chlorite and zinc chloride.
- iii. Listerine Mouthrinses (J&J) – Only those that say “ANTISEPTIC” on the yellow banner are ADA/CDA accepted for plaque and gingivitis reduction: **Cool Mint, Freshburst, Naturals, Original, Soft Mint and UltraClean are all effective in reducing gingivitis by 25-36% in addition to toothbrushing. Don’t dilute!!**

Directions: Rinse with 20ml twice daily for 30 seconds, pH = 4.2

LISTERINE HEALTHY WHITE Restoring, Gentle & Vibrant – 2% H₂O₂, alcohol 10.5%, and 0.0221% NaF designed for 10ml 2x daily use. Contains NO anti-gingivitis (EO) ingredients

LISTERINE AGENT COOL BLUE – alcohol free disclosing rinse for use prior to brushing twice daily. FD&C Dye No. 1 is the disclosing agent.

- iv. Chlorhexidine 0.12% [Peridex (Omnii)], [Periogard (CP)], [Chlorhexidine 0.12% rinse (Teva or Barre)] – ADA/CDA accepted anti-plaque and gingivitis

The standard for comparison for plaque and gingivitis reduction.

Ingredients: Chlorhexidine gluconate 0.12%, 11.6% ETOH, pH = 5.6

Directions: Rinse with 15ml twice daily. Foaming agents inactivate chlorhexidine.

Advantages: Substantivity, lack of toxicity, broad spectrum of antimicrobial activity

Disadvantages: Staining, increased calculus formation, alcohol content, taste, unstable in toothpaste due to inactivation by anionic surfactants such as SLS

Chlorhexidine 0.12% alcohol free and therapeutically equivalent (Sunstar America) and pH is 5.1

PRODUCTS FOR MANAGING ORAL MALODOR

I. CAUSES OF ORAL MALODOR

A. Non-oral causes

- Systemic Sources – diabetes, high protein/low carb diets, renal or hepatic failure, sinus infections, internal bleeding
- Medications that cause malodor – Antabuse, DMSO, Griseofulvin, Isosorbide dinitrate
- Xerogenic Medications – antidepressants, antihypertensives, CNS stimulants, narcotics

B. Dental Causes of oral malodor

- Gingivitis, periodontitis, gross carious lesions, subgingival/tongue plaque, tonsilloliths
- Bacteria include Treponema denticola, Porphyromonas gingivalis, Prevotella intermedia, Tannerella forsythensis, Porphyromonas endodontalis, and Eubacterium species

II. TESTING FOR ORAL MALODOR

- A. Organoleptic Testing – sniff or smell patient's mouth and nose air-scale 0-5
- B. Halimeter by InterScan (Chatsworth, CA) is an "electronic nose" for VSCs

III. TREATMENT FOR ORAL DISEASES – TONGUE CLEANERS

- A. Orafresh Tongue Blade – pediatric and adult sizes, Alwin Enterprises, 800.749-4553
- B. Oolitt – bendable and low profile loop cleaners, Deep Trading Corp, 813.931.0390
- C. Denteco – disposable razor-like, Denteco, Inc., 508.755.0804
- D. Dr. Weider's – tung brush and gel, Peak Enterprises, www.tungbrush.com
- E. Dr. Tung's – stainless steel arch/padded grippers or single handed, Dr.Tung's
- F. Vista – disposable razor-like, Vista, Inc., 414.636.9755
- G. Sakool – bendable plastic rod, U.S. Dentek Corp., 800.433.6835

IV. CHEMICAL PRODUCTS EFFECTIVE FOR ORAL MALODOR REDUCTION

- A. Zinc Salts (chloride, citrate, acetate) – sustained breath odor reduction for 3 hours
 - a. Toothpastes – TriOral, Listerine Tartar Control, Viadent Advanced Care, Aim TC, Close-Up TC, Kiss My Face Tartar Control, Smart Mouth Toothpaste
 - b. Mouthwashes – Lavioris, Listermint, Listerine Tartar Control
- B. Chlorine Dioxide (sodium chlorite) – sustained breath odor reduction for 5 hours
 - a. Toothpastes – Oxyfresh, CloySys II, Therabreath, Profresh,
 - b. Mouthwashes – Oxyfresh, CloSys II, Therabreath, Enfresh, Profresh
- C. Essential Oils of Listerine (menthol, thymol, eucalyptol) – sustained breath odor reduction for 3 hours
 - a. Toothpastes – Listerine EC paste and gel, Breath-So-Fresh Toothpaste
 - b. Mouthwash – Listerine EC Mouthwash, many store brands
- D. Combinations of two of the above effective ingredients
 - a. Smart Mouth – chlorine dioxide and zinc chloride mouthwash www.smartmouth.com
 - b. Breath-So-Fresh – essential oils and zinc chloride
 - c. Oxyfresh with Zinc – chlorine dioxide and zinc chloride www.badbreathcenter.com

V. Product Lines Promoted for Halitosis Treatment

<u>CHEMICAL</u>	<u>MANUFACTURER</u>	<u>PRODUCT LINE/CHARACTERISTICS</u>
COMBINATIONS		
1.) Chlorine Dioxide & Zinc		
TheraBreath	TheraBreath Global www.therabreath.com	Toothpaste, Oral Rinse, Breath Strips, Chewing Gum, Zox Mints, Mouth Sprays
Oxyfresh	Oxyfresh Worldwide Inc. www.oxyfreshww.com	Toothpaste-Flouride/Non-Flouride, Mouth rinse, Dental Gel, Breath Mints, Tongue Scraper, Relief Gel
Breeze	BreezeCare www.breezecare.com	Toothpaste, Breath Strips, Mouthrinse
KFORCE	BreezeCare	Pre-Rinse, Mouthwash, Lozenges
ProFresh	ProFresh www.profresh.com	Mouthwash-0.003%
CloSYSII	Rowpar Pharmaceuticals Inc. www.rowpar.com	Toothpaste, Oral Spray, Oral Rinse
EnFresh	www.enfresh.com	"Trizox" compound, Tongue gel, tongue brush, mouth rinse
BreathGel	International Dental Design Specialist, Inc.	'ZyClor' compound, tongue cleaner, mouth rinse
TriOral Professional SmartMouth Retail	TriOral www.trioral.com www.smartmouth.com	Mouthrinse in two 473ml bottles. The green bottle is zinc and the white bottle is chlorine dioxide. Now travel packets and toothpaste.
2.) Zinc Compounds		
BreathRx (CPC and Zinc rinse, zinc toothpaste)	Philips acquired Discus Dental www.philipsoralhealthcare.com	Mouthwash, toothpaste, gumballs, mints, spray and tongue cleaner
Arm & Hammer P.M.	Church & Dwight Co.	Toothpaste
TriOral Action	TriOral	Toothpaste, Gum, Mints
3.) Essential Oils		
Listerine	Johnson and Johnson www.listerine.com	Toothpaste, Mouthwash, PocketPaks Pocket Mist, Breath Strips
TheraBreath	TheraBreath Global	Rinse, Breath Strips, Gum, Toothpaste, Kit
4.) Triclosan		
Colgate Total Series	Colgate-Palmolive	Toothpaste
5.) Naturals/Herbals		
Good Breath	Scandinavian Formulas	Soft Gel Tablets
Healthy Teeth and Gums	The Natural Dentist www.thenaturaldentist.com	Toothpaste, Oral rinse
Tooth & Gum Tonic	Dental Herb Company	Oral rinse, dentifrice
Tom's Natural	Tom's of Maine	Mouth rinse, toothpaste
Desert Essence Tea Tree Oil	Country Life	Mouth spray, tea tree ingredient found also found in toothpaste, mouthwash

V. STEPWISE APPROACH TO TREATMENT OF ORAL MALODOR

- A. Good subgingival plaque control and twice daily tongue cleaning – **NOT BRUSHING!!**
- B. Add zinc toothpaste twice daily. Increase zinc use with mouthwash as needed
- C. Switch mouthwash to chlorine dioxide if response is not adequate to B.
- D. Switch to chlorine dioxide toothpaste and a combination of chlorine dioxide and zinc mouthwash if C is not adequate. Maintain twice daily tongue cleaning.

Xerostomia (Dry Mouth) Patient Handout

Cindy L. Marek, PharmD, FACA, Associate Professor (Clinical)
Department of Oral Pathology, Radiology and Medicine
The University of Iowa Colleges of Dentistry and Pharmacy
Fall 2019

DEFINITION & CAUSES

Xerostomia (pronounced “zero-sto’me-ah”) is the medical word for the sensation of dry mouth often due to decreased or absent saliva. Saliva is important for hydration, lubrication and cleansing in the oral cavity. The components of saliva aid in digestion, maintain the health of the oral mucosa and help prevent tooth decay.

Dry mouth is a common problem and is caused by a variety of medical conditions and medications. Many drugs, including antihistamines, antidepressants, blood pressure medications and opioid analgesics are known to cause xerostomia. Dry mouth can also be caused by head and neck radiation, depression, anxiety and some autoimmune diseases.

HELPFUL SUGGESTIONS

The lifestyle modifications listed below can help relieve dry mouth symptoms.

Avoid the following:

- a. Caffeine
 - Daily high doses of caffeine can contribute to dry mouth. Make sure all of your beverages (coffee, tea, etc.) are caffeine free.
- b. Alcohol and alcohol containing mouthwashes (read labels carefully)
 - Many commercial mouthwashes contain alcohol which may stimulate salivation but can irritate the tissue.
 - Biotène® and Oasis® make mouth rinses specifically for dry mouth. ACT® Total Care Dry Mouth rinse contains fluoride.
- c. Acidic beverages and foods
 - Carbonated beverages, vitamin waters, energy and sports drinks are very acidic. Without the neutralizing ability of saliva, these drinks erode the teeth and can make your mouth sore. Constant sipping of acidic beverages is especially problematic.
 - Foods and candies high in acid content (citrus fruits, tomatoes, lemon drops, etc.) cause dental decay and may irritate the soft tissue of your mouth.
- d. Gum, candy, cough drops and beverages that contain sugar
 - Sugar, especially in retentive (sticky) form is very damaging to the teeth. Sucrose feeds bacteria that cause cavities.
 - Look for products that contain xylitol (a sweetener that does not cause cavities). Xylitol gums (Spry®, Xyloburst®) when chewed frequently, may inhibit cavity causing bacteria.
 - Avoid gums, candies and oral care products that contain cinnamon as it is a common irritant.
- e. Toothpastes with harsh chemicals or strong flavoring agents
 - Many toothpastes advertised for tartar control, whitening etc. contain pyrophosphates and other chemicals that can damage dry oral tissues.
 - Sodium lauryl sulfate (SLS) is a foaming agent/detergent that is found in most toothpastes. This detergent is well-recognized as a cause of intraoral tenderness and ulceration. We recommend toothpastes that are SLS-free and contain either low levels or no pyrophosphates (Squiggle Enamel Saver Toothpaste, Closys with Fluoride)

Try the following:

- a. Hydration - inadequate hydration can be an important factor in having dry mouth symptoms
 - Sip cool water throughout the day, let ice chips melt in your mouth (never chew ice!).
 - Many people don’t drink enough fluids and this will contribute to a dry mouth.
 - Constant, daily hydration is very important
- b. Try drinking whole or 2% milk with meals.
 - Milk containing fat has moisturizing properties that can aid in swallowing.
 - Patients who cannot drink cow’s milk may find similar benefit in almond or soy milk
- c. Use a cool air humidifier in the bedroom – clean and change water daily
 - Start the humidifier 1-2 hours before bedtime and run continuously throughout the night. The extra humidity can help keep your mouth more comfortable and allow you to sleep through the night. This is of benefit even if you have a humidifier attached to your furnace.
- d. For dry lips, highly purified lanolin products (Lansinoh®) are good lip moisturizers.
 - Chronic use of petrolatum type products on dry lips can be counterproductive.

- Moisturizing lip balms we recommend include Blistex Herbal Answer[®], Blistex Complete Moisture or Banana Boat with Aloe Vera and Vitamin E[®].
- Many dry lip products contain chemicals that can cause irritation or dryness. The need to frequently reapply lip balm is a good indicator that the product is not helpful.
- e. If possible, sleep on your side to reduce mouth breathing.
- f. See your dental practitioner frequently.
 - People with dry mouth are much more prone to oral health problems including oral yeast infections and tooth decay. Excellent oral hygiene is necessary to prevent cavities and gum disease.
 - Your dentist may use tooth sealants, prescription fluoride toothpastes and other interventions that will help prevent oral health problems.
 - Report any unusual oral soreness or burning sensations to your dentist.

COMMERCIAL SALIVA SUBSTITUTES, STIMULANTS AND MOISTURIZING GELS

The products listed below are available without a prescription and can be found or ordered from many pharmacies. These products are often helpful in alleviating the discomfort of dry mouth. They can be used as often as needed and do not interfere or react with other medications. Here are a few examples of products we recommend:

- a. SalivaSure[™] Tablets (Scandinavian Formulas, Inc) – 90 ct. bottle
 - To stimulate natural saliva flow, dissolve one tablet slowly under tongue up to every hour as needed.
 - Highly recommended, will not cause cavities or sore mouth. Easy to carry, no drug interactions.
 - This product is available at the Dental Pharmacy and does not require a prescription.
- b. Biotène[®] Products (GlaxoSmithKline)
 - Oralbalance[®] Gel – 1.5 oz tube – has a soothing effect on oral tissue, can be used under dentures to improve comfort. Rinse mouth with water, then spread thin film over affected tissues. Can be used as often as needed.
 - Biotène[®] Moisturizing Mouth Spray – 1.5 oz. spray bottle. Shake well and spray directly into mouth as needed.
 - Oralbalance[®] Dry Mouth Moisturizing Liquid – 1.5 oz squeeze bottle. Squeeze several drops directly into mouth as needed.
- c. Elevate Oral Care Products – All Day Dry Mouth Spray, Epic Toothpaste with Sodium Fluoride
- d. **3M Xerostomia Relief Spray-now available from wholesalers like Patterson and Henry Schein**

COMMERCIAL OVER THE COUNTER (OTC) TOOTHPASTES

Avoid toothpastes that make claims on whitening or tartar control as they often contain ingredients that are irritating to the oral mucosa. Most OTC toothpastes contain detergents (sodium lauryl sulfate (SLS), cocamidopropyl betaine etc.) that irritate oral mucosa as mentioned above. We recommend detergent-free toothpastes:

- Squigle Enamel Saver Toothpaste –contains xylitol and fluoride
- Tom’s of Maine for Kids Strawberry with fluoride
- Prevent Dry Mouth 5000ppm toothpaste (RX only)

PROFESSIONALLY DISPENSED PRODUCTS

- a. GC Dry Mouth Gel (GC America) – 40 g. tube. Rinse mouth with water, then spread thin film on affected tissue as needed. Similar to Oralbalance[®] gel. Available in 5 mild flavors.
- b. MI Paste[™] and MI Paste Plus[™] - 40 g. tube. Rinse mouth with water, then spread pea-sized amount over teeth and tissue. (This product requires a prescription from your dentist or physician)
 - These products were developed to help rebuild tooth structure, but have the additional effect of soothing dry intraoral tissue. *Cannot be used by people with casein (milk protein) allergies.*
 - Especially useful at bedtime and probably the best product for “comfort” that we have right now.
- c. DentiCare Pro-Gel by Medicom is a 5000ppm neutral NaF gel with no flavors or dyes-use in trays

Therapeutic Agents and Treatment Strategies for the Management of Selected Mucosal Diseases

July 2019

Cindy Marek, PharmD & Faculty,
Dept. of Oral Pathology, Radiology & Medicine
The University of Iowa College of Dentistry

Footnote Key:

1. These medications are all contraindicated in microbial diseases. If given to patients with microbial diseases, microbial proliferation is usually enhanced and systemic dissemination is possible. Candidosis is a common side effect.
2. Systemic steroids are contraindicated or must be used with caution in a number of systemic conditions. Consultation with the patient's physician is recommended before prescribing. Tapering of prednisone is not necessary with 5-7 day burst therapy. Tapering of prednisone is not necessary with alternate day therapy (QOD) if the dosage does not exceed 20 mg QOD. In order to reduce the possibility of adrenocortical suppression, it is important that prednisone be taken in harmony with diurnal adrenocortical steroid levels. In order to accomplish this, prednisone should be taken 1-1/2 hours after normal arising time. Alternate day AM (QOD) dosage also reduces the possibility of adrenocortical suppression.
3. Whenever topical mouth rinses or ointments are prescribed, the manner in which the medication is used is very important. The patient should be advised that the medications are effective on contact and that they should avoid anything by mouth (NPO) for 1/2-1 hour after using them to prolong medication contact time.
4. Baseline hematology laboratory studies to include platelets are necessary to monitor possible bone marrow suppression.
5. Hepatotoxicity has been reported.

OPRM Faculty

* Denotes prescription items that must be extemporaneously compounded by a pharmacist. Usually a specialty "compounding pharmacy" is a better choice as they have more experience and knowledge regarding product formulation.

Extemporaneously Compounding Medications for Intraoral Conditions

- Few products available in the U.S - ?? limited product demand
- Problems:
 - Difficulty with insurance payments, XIX & Medicare will not reimburse for the full cost
 - Expensive – Dental Pharmacy can mail Rxs to patients living in Iowa – at significantly less cost to patient patients and the products are formulated correctly for improved efficacy
 - "I can do that" - generalized lack of knowledge – many pharmacies incorrectly compound intraoral products causing mucosal irritation, reduced efficacy
- Make sure products are not flavored or sweetened (especially with sucrose) unless necessary!

I. CHRONIC NON-MICROBIAL MUCOSITIS

(aphthous stomatitis, erosive lichen planus, mucous membrane pemphigoid, pemphigus, erythema multiforme)

Mouth rinses: Magic mouth rinse, miracle mouth rinse, 1, 2, 3 mouth rinse, special mouth rinse formulas, etc.

DON'T bother!! WHY: Dilution effect from mixing commercial products renders them ineffective

- *Nystatin 12,500 units/ml*
 - Normal nystatin 100,000/ml
 - 8 fold decrease from our minimum therapeutic agent
- *Benadryl 1.25 mg/ml*
 - 7.5 mg fairly low dose too
 - 25 mg much more commonly used
 - Does give a topical anesthetic effect at least in the higher concentrations
- *Hydrocortisone*
 - Hydrocortisone 0.25 mg/ml
 - 10 fold decrease from dexamethasone 0.5mg/5ml
 - 20 fold decrease from 0.1% triamcinolone acetonide suspension
- *Kaopectate®*
 - Older formulation of Kaopectate® used an attapulgitte clay to coat the mucosa. This product has been reformulated and now contains bismuth subsalicylate, which can cause a grayish-black discoloration of the tongue and is contraindicated in patients with hypersensitivity to salicylates.

Baseline initiatives to allow therapies to work:

- *Decrease common possible irritants – Avoid:*
 - Pyrophosphates
 - Cinnamon
 - Menthols, phenols, etc.
- *Maintain “salivary pellicle”*
 - Avoid sodium lauryl sulfate (SLS) in dentifrices
 - Avoid EtOH if possible
- *Maintain saliva*
 - Xerogenic agents
 - Hydration
- *Manage bugs*
 - Bacteria
 - Fungi

Mouth rinses^{1,3}

RX: Dexamethasone 0.5 mg/5ml oral solution¹ (West-Ward)
Disp: 240 ml
Sig: Rinse with 5 ml for 1 min. and expectorate QID, PC (after meals) and HS (before retiring). NPO 1\2 hr

- Commercial product covered by insurance companies
- Specify West-Ward brand, others are elixirs (5% or> EtOH)
- Use correct strength to avoid toxicity
- Biologic half-life 36-54 hours

***RX:** Triamcinolone acetonide (micronized) 0.1 OR 0.2% aqueous suspension¹
Disp: 240 ml
Sig: Rinse with 5 ml for 1 min. and expectorate QID, PC (after meals) and HS (before retiring). NPO 1\2 hr.

- *About 2 x stronger than the commercial dexamethasone*
- Use the 0.2% for more severe cases
- Better effect if made with micronized powder at Dental Pharmacy vs. commercial in Kenalog[®] inj. (also much less expensive \$26.96 at DP vs. \$250 w/ Kenalog[®])

***RX:** Triamcinolone acetonide (micronized) 0.1 OR 0.2% in nystatin 100,000 U/ml suspension
Disp: 240 ml
Sig: Rinse with 5 ml for 1 min. and expectorate QID, PC (after meals) and HS (before retiring). NPO 1\2 hr.

- Use in patients predisposed to candidosis
- Commercial nystatin suspension is 30-50% sucrose
- We make a sugar-free nystatin suspension at the COD
- (\$36.10 at DP)

***RX:** Triamcinolone acetonide (micronized) 0.1 OR 0.2% in amphotericin-B 15mg/ml suspension
Disp: 240 ml
Sig: Rinse with 5 ml for 1 min. and expectorate QID, PC and HS. NPO 1\2 hr.

- Use in patients predisposed to candidosis
- Our amphotericin-B suspension is sugar-free
- More efficacious than nystatin suspension
- Use amphotericin-B 25 mg/ml if needed
- (\$69.95 at DP)

Ointment^{1,3}

RX: Triamcinolone acetonide 0.1% OR 0.5% ointment
Disp: 15 gm
Sig: Apply thin film to inner surface of dentures or medication trays up to QID, NPO 1/2 hr.

- We usually use higher potency steroids in trays

- Low to medium potency steroid, price \$18
- Use 0.1% strength on lips and dermis
- Still fluorinated and can thin lips or dermis long term
- Choose desonide instead for chronic use
- Seat trays for 30 min., then rinse mouth

RX: Fluocinonide 0.05% OR clobetasol 0.05% ointment
Disp: 15 gm
Sig: Apply thin film to inner surface of dentures or medication trays BID. Seat for 30 minutes

- High potency steroids, commercial products
- Instruct patients to expectorate & rinse mouth thoroughly after use
- Price of commercial products \$70-150 for 15 g tube

Occlusive Ointment^{1,3}

Note: Orabase Maximum Pain Reliever Paste[®] (Colgate) with 20% benzocaine is no longer on the market.

- Similar products such as Oral Pain Reliever 20% Paste[®] (CVS Health) and RITE AID Toothache Pain Relief 20% Paste[®] (Rite Aid Corp.) contain 20% benzocaine, and are made in an oral adhesive base but do not have the same ingredients as the original Orabase.[®]

***RX:** **Triamcinolone acet. 0.5% ointment 1:1 with Oral adhesive base**

Disp: 20 gm

Sig: Apply thin film to dried mucosa BID-QID, PC & HS Do not rub in. NPO 1/2 hr.

- Lower potency mixture due to 1:1 dilution
- Prescribe ointments to mix with oral adhesive bases
- Rubbing may cause the product to become grainy & lose elasticity

RX: **Triamcinolone 0.1% Dental Paste[®]**

Disp: 5 gm tube

Sig: Apply thin film to dried mucosa QID. Do not rub in. NPO 1/2 hr.

- Commercially available but cost to patient without insurance is \$80 per 5 gram tube!
- Low concentration of triamcinolone
- Good “bandage” effect, useful in pediatric patients

***RX:** **Clobetasol 0.03%, 0.06% or 0.1% in Jelene compounded ointment 1:1 with Oral adhesive base**

Disp: 20 gm

Sig: Apply thin film to dried mucosa BID. Do not rub in. NPO 1/2 hr.

- Allows for various concentrations of clobetasol, including higher concentrations than obtained by mixing commercial products 1:1 with oral adhesive base

Combined Anti-inflammatory & Antimycotic Topical Agents¹

***RX:** **Clobetasol 0.05%, clotrimazole 2% in Jelene oint.**

Disp: 15 g

Sig: Apply thin film inner surface of dentures or medication trays BID. Seat for 30 minutes. Rinse mouth thoroughly after use

- Compounded from drug powders (not a 1:1 mixture)
- Allows for 2x commercial strength of clotrimazole
- Can customize strengths of both agents
- Ointment formulation is more occlusive than creams

Systemic and Intralesional Steroids

RX: **Prednisone 5 mg, 10 mg, 20 mg tabs^{1,2}**

Disp: #

Sig: 40mg PO q A.M. (1-1/2 hrs after normal arising time) x 5 days followed by 10 mg QOD A.M. x 10 days

- Short bursts \leq 3 weeks don't require taper
- Best taken with food

- Dose range 40-80 mg per day, depending on professional judgment; generally for severe acute cases such as erythema multiforme or initial therapy for long term unmanaged pemphigus, lichen planus or pemphigoid
- When daily dose is 30 mg or greater patients may experience insomnia, headache or irritability

RX: **Triamcinolone acetonide injectable 40 mg/ml (Kenalog[®]) diluted to 10 mg/ml or use Kenalog 10 mg/ml strength¹**

Directions: Inject 10-40 mg (shake syringe immediately before use)

- Of value in management of solitary lesions recalcitrant to topical or systemic steroids

- Best mixed with local anesthetic with epinephrine as the diluent
- Area should be anesthetized before injection of triamcinolone acetonide suspension if local anesthetic is not used.

II. MUCOUS MEMBRANE PEMPHIGOID

Anti Collagenase Agents

RX: Doxycycline or minocycline 100 mg tabs/caps

Disp: #30

Sig: Take QD or BID with food and plenty of water.

- Avoid taking HS – esophageal irritant

- Use as an adjunct to steroid therapy in patients
- Avoid taking with antacids, iron, calcium tablets
- Nicotinamide has similar actions but requires close monitoring by a specialist
- FDA pregnancy category: D

III. APHTHOUS STOMATITIS

Pathophysiology: Immunologic

- *Location: nonkeratinized, unattached mucosal surfaces*
 - Typically buccal vestibule, lateral or ventral tongue, floor of mouth
- *Heals in a predictable manner*
 - Types: minor, major, herpetiform
 - Treatment not usually necessary for the common minor type

- *Precipitating Factors:*

Cinnamon Oil

Genetics

Minor Oral Trauma

Medications

Stress

Dentifrices

Sodium Lauryl Sulfate (SLS)

Estrogen Shifts

Primary Prevention Factors:

- Relate to maintenance of salivary pellicle or impeding the recognition of antigens to the immune system

Pharmacotherapeutic Management Choices:

- *Topical Route*
 - Treatment of choice: triamcinolone acetonide rinse - alters course of disease, increases healing rates
 - Steroid ointments, pastes
- *Systemic Route*
 - Prednisone - for difficult cases, large +/- multiple ulcerations
- *Over-The-Counter Products*
- *Inappropriate Chronic Treatment*
 - Cautery agents - do not affect course of disease (Debacterol[®], silver nitrate, Negatan[®], laser)
 - Tetracycline rinses, oral antibiotics etc.
- *Sodium Lauryl Sulfate (SLS) Free Dentifrices*
 - Sodium lauryl sulfate (aka: sodium dodecyl sulfate, SDS) is a surfactant (foaming agent) found in most commercially available toothpastes and gels
 - Causes dose-dependent epithelial desquamation
 - Note: All SLS free products are not appropriate for some patients due to pyrophosphate content
 - Cocamidopropyl betaine (CABP or CPB) - surfactant that is less irritating to tissue than SLS
 - RX: Prevident[®] 5000+ Dry Mouth, 100 g container (only SLS free Prevident[®] product)
 - Note: For overdenture abutments use only Prevident gel (56 g tube), not a dentifrice (does not contain surfactants or abrasives)

- OTC dentifrices with CAPB
 - Biotène® (GSK) Fresh Mint Original Formula
 - Biotène® (GSK) Gentle Mint Formula
 - Sensodyne® (GSK) products (except Deep Clean which contains SLS)

- **Squigle® Enamel Saver Toothpaste** Our toothpaste of choice
 - Very mild dentifrice – no tartar control agents or irritating flavors (mild mint)
 - Uses poloxamer as surfactant – very mild
 - Can be difficult to find in retail stores, may be obtained online or mailed from D. pharmacy

IV. CANDIDIASIS

Topical Suspensions³

RX: Nystatin oral suspension 100,000 U/ml

Disp: 12 day supply (240 ml)

Sig: Rinse with 5 ml for 1 minute and expectorate P.C. (after meals) and HS (before retiring) NPO 1/2 hr.

- Poor antifungal
- Commercial products contain 33-50% sucrose, not recommended for this reason, especially in chronic/recurrent cases like Sjögren's, medicament xerostomia or post radiation xerostomia, (\$60+)

***RX:** Nystatin oral suspension 100,000 U/ml Sugar-Free

Disp: 12 day supply (240 ml)

Sig: Rinse with 5 ml for 1 minute and expectorate P.C. (after meals) and HS (before retiring) NPO 1/2 hr.

- Viscous, will coat tissue
- Compounded at Dental Pharmacy (\$35)
- Must be refrigerated, shorter shelf life than commercial, but not cariogenic

***RX:** Amphotericin-B oral suspension 25mg/ml

Disp: 14 day supply (280 ml)

Sig: Rinse with 5 ml for 1 minute and expectorate P.C. (after meals) and HS. (before retiring) NPO 1/2 hr.

- Much more effective than nystatin suspension
- Of use for fluconazole-refractory infections or when *C. krusei* or *C. glabrata* are suspected
- May use 15mg/ml strength when combining with triamcinolone acetonide

Ointment³

RX: Nystatin ointment 100,000 U/g

Disp: 15 gm

Sig: Apply thin film to inner surfaces of dentures and angles of mouth QID, PC & HS. NPO 1/2 hr.

- Poor antifungal
- Works OK under dentures, but not first line agent
- Bright yellow color may be objectionable for angular cheilitis, (\$24)

***RX:** Clotrimazole 2% in Jelene ointment

Disp: 30 g

Sig: Swab or apply thin film onto affected area QID, PC and HS, NPO 1/2 hr.

- Useful for debilitated patients who cannot rinse
- Higher concentration (2%) and more occlusive than commercial creams (no commercial oint. available)
- Compounded at Dental Pharmacy

Troches³

RX: Clotrimazole 10 mg oral troches

Disp: 70 troches

Sig: Dissolve 1 troche in mouth every 3 hours while awake (5 tabs per day). NPO 1/2 hr. after use.

- Patients with decreased salivary flow should rinse mouth with water prior to use to enhance dissolution

- Compliance problems with 5X daily therapy
- 1-2 troches QD HS is useful for maintenance or prevention. (\$120)
- Can also dissolve 2 troches in am, 1 in afternoon and 2 HS to improve compliance
- Contains sucrose, FDA pregnancy category: C

Buccal Tablet

RX: Miconazole 50mg buccal tablet (Oravig®)

Disp: 14

Sig: Apply tablet to canine fossa once daily for 14 days

- Approved for patients 16 years and older
- Cost >\$900/14 tablets, insurance usually will not cover

Angular Cheilitis

- OTC clotrimazole 1% cream works – patient must understand that even though it is marketed for athlete's foot
- RX for clotrimazole 2% ointment (Jelene) – doubles the strength of clotrimazole

Cream³

RX: Clotrimazole 1% cream (Rx, OTC as Lotrimin AF®, g)

Disp: 15 gm Rx or 12 gm OTC

Sig: Apply thin film to inner surface of denture and angles of mouth QID. NPO 1/2 hr. after use.

- Has slight anti-staph activity
- Available OTC (\$7) but labeled for athletes foot and jock itch which may cause some patients to hesitate.
- Identical to Rx version (\$28)

***RX:** Clotrimazole 2% in mupirocin 2% ointment

Disp: #20 g

Sig: Apply thin film to corners of mouth three times daily (after breakfast, mid-day and at bedtime. NPO for 30 min. after use

- This combination works well if the problem has been persistent or there is redness (secondary to skin staph and strep)
- Use until clear plus 4 days

***RX:** Clotrimazole 1% cream 1:1 mupirocin ointment (Bactroban®)

Disp: #15 g

Sig: Apply thin film to angles of mouth 3 times daily (after breakfast, in pm & HS). NPO 30 min. after use. Apply with cotton-tip applicator.

- Use until clear plus 4 days
- If applied with finger, wash hands after use.

- Most pharmacies will combine two commercial products. Commercial 1% clotrimazole is only available in cream.
- Combination of ointment & cream is not ideal, but mupirocin cream may cost >\$200/15 g while ointment is \$20.
- Better choice than Mycolog II which is >\$100/15 g

Systemic⁵

RX: Fluconazole 100 mg tablets

Disp: #11-15 tabs

Sig: Take 1 tablet BID for first day, then take 1 tablet daily for 10 – 14 days.

- Loading dose results in steady state concentration in 2 days
- Price of 15 tablets is approximately \$65 without insurance, cheaper to break 200 mg tablets in half

- Potent CYP2C9 inhibitor, moderate CYP3A4 inhibitor, causes QT prolongation
- Serious interactions with statin drugs, psych drugs, sulfonyleureas, warfarin, some antihypertensives and many other drug classes – always check for interactions before prescribing
- FDA pregnancy category: X Even single doses in 1st or 2nd trimester can cause miscarriage

Antibacterial Mouth Rinse³

RX: Chlorhexidine 0.12% oral rinse (Peridex[®], g)

Disp: 473 ml

Sig: 10 - 15 ml mouth rinse for 30 seconds and expectorate BID (after breakfast and HS), NPO 1\2 hr.

RX: Alcohol-Free Chlorhexidine 0.12% oral rinse (Pareox[®])

Disp: 473 ml

Sig: 10-15 ml mouth rinse 60-90 seconds and expectorate BID, PC, AM & HS. NPO 1/2 hr.

- 11.6% alcohol content will irritate ulcerations and enhance xerostomia, (\$4-14)
- Due to chemical deactivation, separate from toothpaste by 30 min.
- FDA pregnancy category: B
- Non-alcohol formulation – useful for alcoholics, patients with mucositis, xerostomia, (\$18)
- Due to chemical deactivation, separate from toothpaste by 30 min.

V. HERPES & HERPES ZOSTER INFECTIONS

Herpes Labialis (Cold Sores, Fever Blisters)

- Virus remains dormant within the dorsal root ganglia until activated
- Asymptomatic viral shedding occurs for several days before the prodromal period & after lesions heal
- Specific triggers:
 - Sunlight (ultraviolet radiation) UVB
 - Tissue injury & inflammation
 - Physical or emotional stress: malnutrition, fever, colds, influenza, menstruation, exposure to extremes in temperature

Systemic Treatment of Herpes Labialis (Immunocompetent Patients)

RX: Valacyclovir 1 g tablets (Valtrex[®], g)

Disp: 4 tablets

Sig: 2 tablets at onset of symptoms, then 2 tablets 12 hours after first dose

- Drug of choice -probably most efficacious therapy to date
- Price of 4 tablets \$20

- A prodrug of acyclovir which is 3 times more bioavailable than acyclovir, may use in patients \geq 12 years of age
- **WARNING:** Use with caution in renal disease, has not been studied in pre-pubescent children
- Headache &/or nausea are dose related side effects (15%)

RX: Famciclovir 500 mg tablets

Disp: 3 tablets

Sig: Take 3 tablets (1500 mg) at onset of prodrome

- Symptom duration decreased by 1.7 days when taken within an hour of onset of prodrome
- Price of 3 tablets \$30, not available in all pharmacies

- Best taken within 48 hours of symptom onset
- Can cause headaches, dizziness, GI upset
- Efficacy & safety haven't been established in patients under 18 years of age, adjust dosage in renal impairment
- 2nd line therapy after valacyclovir
- FDA pregnancy category: B

Topical Treatment of Herpes Labialis (Immunocompetent patients)

Ointments and Creams

- *Topicals are MUCH less efficacious than oral (systemic) therapy, prohibitively expensive and **not recommended** but included here for completeness.*
- Topical creams and ointments are not appropriate for intraoral use

OTC: Docosanol 10% cream (Abreva[®])

2 gm tube

Directions: Apply 5 times daily at onset of symptoms until lesions heal

- Recurrent HSV labialis studies (2) demonstrate mean duration of lesions & pain \downarrow by $\frac{1}{2}$ to 1 day
- ??? Efficacy compared to other topicals
- Cost: \$21/2 g tube

RX: Penciclovir 1% cream (Denavir®)
Disp: 5 gm tube
Sig: Apply every 2 hrs (9 times/day) during waking hours for 4 days beginning at the onset of symptoms

- 1997 study demonstrate ↓ mean duration of lesions & pain ↓ by 1 day.
- More efficacious than acyclovir ointment
- Cost: >\$895/5 g tube

RX: Acyclovir 5% cream or ointment (Zovirax®,g)
Disp: 5 gram tube cream (Zovirax®) 5 gram tube ointment
Sig: Apply thin film every 3 hrs (six times daily) at the onset of symptoms and continue for 7 days

- Little benefit, duration of Sx. decreased by ½ day
- 5 g tube of Zovirax® cream \$805, 5 g tube 5 g tube generic ointment \$300
- Recurrent HSV labialis shows no clinical benefit, but some ↓ in viral shedding
- Is NOT effective in prevention of recurrent herpes labialis

Oral buccal tablet

RX: Acyclovir 50 mg buccal tablet (Sitavig®)
Disp: 2
Sig: Apply tablet to the upper gum region (canine fossa) within 1 hr after onset of prodromal symptoms.

- Study: mean duration of herpes labialis episodes were decreased by ½ day compared to placebo (\$315/2 tablets)
- Patients experienced 35% aborted episodes
- Place on canine fossa and hold in place with slight pressure on the upper lip for 30 sec. to ensure adhesion.
- Apply to ipsilateral to symptoms
- Single application per episode
- Contraindication: allergy to casein (milk protein)

Systemic Agents for Primary & Recurrent HSV Gingivostomatitis (Immunocompetent Patients)

- Acute herpetic gingivostomatitis can occur on both movable and attached oral mucosa. Recurrent infections in healthy patients are usually limited to attached gingival and hard palate
- *It is important to note that the duration of treatment for a primary case of HSV gingivostomatitis vs a recurrent case is different. Recurrent cases require shorter durations of treatment!!!*
- Short term therapy is indicated for patients who get recurrent herpetic after prolonged sun exposure, dental treatment, etc. Therapy must be initiated before exposure to any triggers. Start the day before trigger exposure and continue for a full course of treatment as listed below.

RX: Valacyclovir 500 mg or 1 g (Valtrex®, g) caplet
Primary HSV Gingivostomatitis :
Sig: 1 gram BID x 7-10 days
Recurrent HSV Gingivostomatitis:
Sig: 500mg BID x 3 days Or 1 g once daily x 5 days

- **WARNING:** Use with caution in renal & hepatic disease
- Approved for 12 years of age and older, limited data in children 2-<12 years of age. Pediatric consult needed for children age 2-6
- Headache & nausea are dose related side effects (15%)

RX: Famciclovir 250 mg or 500 mg tablets
Primary Gingivostomatitis HSV:
Sig: 250 mg TID x 7-10 days
Recurrent Gingivostomatitis HSV:
Sig: 1000 mg BID x 1 day Or 125 mg BID x 5 days

- Can cause headaches, dizziness, GI upset
- Best taken within 48 hours of symptom onset
- Efficacy & safety haven't been established in patients under 18 years of age

RX: Acyclovir 400 mg (Zovirax®, g) tablet
Primary HSV Gingivostomatitis:
Sig: 400 mg 3 times daily for 7-10 days
Recurrent HSV Gingivostomatitis:
Sig: 400 mg 3 times daily for 5 days

- Only effective if initiated very early in recurrence
- **WARNING:** Use with caution in renal impairment, dehydration
- FDA pregnancy category B
- Pediatric consult needed for children ages 2-6.

Or 800mg 3 times daily for 2 days

- Primary gingivostomatitis in children: Acyclovir 20mg/kg PO QID (max of 400 mg per dose) for seven days based on limited data – low level of evidence

Prophylaxis for Recurrent HSV Infections (Immunocompetent Patients)

Prophylaxis for recurrent herpes labialis (RHL) and gingivostomatitis using oral antivirals:

- Long term prophylaxis is indicated if patients have at least six or more herpetic outbreaks per year. Reassess need every 6 – 12 months.

RX: Valacyclovir 500 mg (Valtrex®, generic)

Disp: 30 caplets

Sig: Take 500 mg daily

- Doesn't appear to have large advantage over acyclovir, but regimen is easier
- Regimen for patients with >9 episodes/year is 1 gram QD

RX: Famciclovir 500 mg (Famvir®, generic)

Disp: 30 tablets

Sig: Take 500 mg BID

- No evidence that famciclovir prevents RHL
- Use valacyclovir

Varicella Zoster Virus (VZV) Infections

- 25-fold decrease in zoster after immunization
- Patients with prior varicella zoster virus infection have a 10% chance of acquiring shingles
- Increased risk of stroke within 6 months of episode, antivirals may have protective effect
- For patients >50 years add prednisone to decrease pain in acute phase of disease
 - Does not decrease incidence of post-herpetic neuralgia
- Trials showing benefit of Rx therapy only in patients treated within 3 days of onset of rash.

RX: Valacyclovir 1 gram (Valtrex®, generic) tablets

Disp: 21 caplets

Sig: Take 1 caplet TID for 7 days

- Agent of choice

- Patients should begin treatment within 48 hours of the onset of symptoms.
- More effective than acyclovir for acute pain cessation and decreasing the frequency of persistent pain.
- **WARNING:** Use with caution in renal impairment

RX: Famciclovir 500 mg tablets

Disp: 21 tablets

Sig: Take 1 tablet every 8 hours for 7 days

- Prodrug of penciclovir, approximately same efficacy and safety as acyclovir

- Patients should begin treatment within 48 hours of onset of symptoms, efficacy after 72 hours is questionable
- **WARNING:** Use with caution in renal function impairment, has not been approved in children <18 years of age
- Equivalent to acyclovir in reduction of acute pain and incidence of PHN

RX: Acyclovir 800 mg (Zovirax®, generic) tablets

Disp: 35 - 50 tablets

Sig: Take 1 tablet q 4 hours (5 tablets per day) for 7-10 days

- Therapy is most effective if started within 48 hrs after the onset of symptoms
- Meta-analysis: acyclovir accelerated by 2-fold pain resolution and reduced incidence of PHN at 3 & 6 months
- Don't use.

VI. LIP CONDITIONS - SUMMARY AND EXAMPLES

NOTE: EVERY PATIENT IS UNIQUE AND WE INDIVIDUALIZE ALMOST ALL THE EXAMPLES GIVEN IN THIS SECTION.

Chapped lips and baseline therapy for other lip problems

- *Moisturizer: Lanolin*
 - Use 3-4 times a day
 - Brand names Lansinoh® or Purelan100® (venture into the breast feeding aisle)
 - Ultra pure (HPA) brands are less allergenic and more efficacious than generic lanolin products
- *Lip balm:*
 - PROBABLY NOT NECESSARY UNLESS GOING OUT IN THE WIND or SUN
 - Prefer Banana Boat® Aloe with Vitamin E (SPF 45) or Blistex® Complete Moisture® (SPF 15)
 - Use when in sun or wind once or twice if in the sun frequently
 - Put this on immediately after the lanolin

Ulcerative conditions of the lips, including idiopathic, lichen planus, pemphigoid etc.

- *Steroids (ointments on vermilion)*
 - Use only nonfluorinated steroids and limit these steroids ONLY for inflammatory or ulcerative conditions confined to the lipstick portion of the lips
 - Rx: desonide 0.05%. Apply very thin layer to lips twice a day
 - PUT ON AFTER LANOLIN
 - DON'T apply to corners of lips
- *Apply for three weeks or until the ulcer is gone*
 - Do not prescribe these products for use > 3 times per year
 - If ulcer resolves but erythema remains start decreasing the application of the steroid cream, per outline below or until erythema resolves
 - First to once a day x 10-14 days, then every other day x 10-14 days, then every third day x 10-14 days
 - If ulcer resolves without residual erythema steroids may be discontinued completely
- *IF THE ULCER IS STILL THERE IN 3 weeks may consider short term ultrapotent steroid:*
 - 1:1:1 Mixture of clobetasol 0.03% ointment and 2% mupirocin (Bactroban, g) ointment and clotrimazole 2% cream

Conditions of the lips occurring outside the vermilion border

- *NON-STEROIDAL AGENTS IN PERIORAL/CIRCUMORAL REGION*
 - Steroids are NOT indicated for circumoral or perioral dermatitis
 - Likewise angular cheilitis cases (covered below) only rarely requires anti-inflammatory agents
- *Creams are preferred on skin surfaces*
 - In these areas outside the vermilion pimecrolimus or tacrolimus may be used
 - NOTE: Due to the “black box” warning associated with these medications, this handout summary will not cover these. If clinician is familiar with restrictions and limitations they may be mixed and used with mupirocin and clotrimazole similar to the clobetasol 1:1:1 mixture above.
- *Treatment of angular cheilitis*
 - Use 2% clotrimazole cream and 2% mupirocin cream (mixed in 1:1 ratio)
 - Apply to lip first thing in the morning and last thing at night

- After the morning application wait about a half hour to apply the lanolin or Blistex Complete Moisture if going outside.
- Don't use the desonide while using this mixture unless consultation for complicating factors is performed. There are numerous cofactors including vertical dimension, obsessive compulsive disorders and perioral rhytides.