

VISN 21 Drug Use Criteria for Non-Formulary use of Nicotine Lozenge August 2004

NAME: Nicotine polacrilex lozenge
SYNONYM: Commit

USES:

Appropriate Indication: Patient has indication for use of nicotine gum (see clinical practice guidelines for Tobacco Use Cessation at: http://www.oqp.med.va.gov/cpg/TUC/TUC_Base.htm), but is unable to use the gum due to:

- Dental problems that may be exacerbated by chewing gum, or
- Temporomandibular joint (TMJ) disease.

Inappropriate Use:

- Allergy to nicotine or any component of the delivery system (i.e. aspartame)
- Continued to use tobacco products
- Pregnancy/lactation

FORMULARY RESTRICTIONS:

- Non-formulary, restricted to drug use criteria

DRUG THERAPY SELECTION:

Efficacy:

1. Nicotine lozenges have been shown to be more effective than placebo in reducing craving and withdrawal symptoms, and increasing abstinence rates.
2. There are no studies directly comparing nicotine lozenges to other forms of NRT

Safety:

1. The most common adverse effects experienced by subjects receiving nicotine polacrilex lozenges were gastrointestinal disorders (diarrhea, flatulence, nausea, hiccups, and heartburn) and respiratory tract disorders (coughing, sore throat, and URI).
2. Mouth ulcers can also result with use of the nicotine lozenge.

Precautions/Contraindications

1. Cardiovascular disease: There are concerns that NRT could cause platelet activation and catecholamine release. NRT is not an independent risk factor for acute myocardial events. NRT should be used with caution among particular cardiovascular patient groups:
 - a. those in the immediate (within 2 weeks) postmyocardial infarction period,
 - b. those with serious arrhythmias, and
 - c. those with serious or worsening angina pectoris.
2. Use of NRT must be carefully assessed and monitored in persons with hyperthyroidism, peptic ulcer, insulin-dependent diabetes mellitus, and certain peripheral vascular disease.
3. See http://www.oqp.med.va.gov/cpg/TUC/TUC_Base.htm and http://www.surgeongeneral.gov/tobacco/treating_tobacco_use.pdf for more details on appropriate candidates for NRT.

COST COMPARISON:

Drug	Acquisition Cost	Dose	Cost/Month/Patient
Nicotine Lozenge 2mg or 4mg	48 count \$21.54 72 count \$30.26	1 lozenge Q 1 to 2 hours (wk 1-6)	\$113.40 to \$252.00*
Nicotine Gum 2mg	110 count \$21.59	1 piece of gum Q 1 to 2 hours (wk 1-6)	\$54.00 to \$144.00**
Nicotine Gum 4mg	110 count \$30.26	1 piece of gum Q 1 to 2 hours (wk 1-6)	\$74.27 to \$198.07**
Nicotine inhaler	168 count \$79.18	1 inhalation (4mg) six to sixteen times/day	\$84.84 to \$226.23
Nicotine nasal spray	~200 applications \$19.64	2-4 sprays (1-2 in each nostril) Q 1 hour, to max 80 sprays/day	\$141.41 to \$235.68
Nicotine Transdermal 7mg, 14mg, or 21mg/24hr	7 count \$12.97	1 patch Q 24 hours	\$51.88

*Calculations based on the range from 9 lozenges (recommended number of lozenges used per day during initial treatment) to the 20 lozenges (maximum per day).

** Calculations based on the range from 9 pieces of gum (recommended number of pieces used per day during initial treatment) to the 24 pieces of gum (maximum per day).

RISKS:

Potential for dispensing errors between lozenges and gum, due to both being nicotine products available in 2mg and 4mg dosage strengths. Patients may also duplicate therapy if taking OTC NRT in addition to NRT dispensed by the VA pharmacy.

DUPLICATIVE THERAPY:

Nicotine gum
Nicotine inhaler
Nicotine nasal spray

DOSING AND ADMINISTRATION:

- Available in 2 mg and 4 mg lozenges
- Starting dose is determined by time to first cigarette (reliable indicator of nicotine dependence).
 - If patient smokes first cigarette more than 30 minutes after awakening, start with 2mg nicotine lozenge.
- If patient smokes first cigarette within 30 minutes of awakening, start with 4mg nicotine lozenge.
- The recommended usage of this agent is 12 weeks. The use of this product longer than a 12-week period is not recommended. If further nicotine replacement is required, please contact a physician.

Dosing Schedule

Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 lozenge Q 1 to 2 hours	1 lozenge Q 2 to 4 hours	1 lozenge Q 4 to 8 hours

- Administration Instructions
 - Do not smoke or use other tobacco products after initiation of the lozenge treatment

- Avoid eating or drinking 15 minutes prior to lozenge use or while the lozenge is in the mouth.
- Do not chew or swallow lozenge.
- The lozenge should be sucked on until dissolution, moving the lozenge from one side of the mouth to the other. It may take up to 20-30 minutes to dissolve.
- Use one lozenge at a time
- Do not use more than 5 lozenges in 6 hours or 20 mg in 24 hours.
- Do not use more than one lozenge at a time or continuously to avoid adverse effects.
- For best results, use at least 9 lozenges per day in the first 6 weeks.

DRUG INTERACTIONS:

- Smoking causes enzyme induction. Smoking cessation may require reevaluation of some medications (i.e. theophylline, imipramine, and certain beta-blockers) that are metabolized via this pathway.

LABORATORY INTERACTIONS:

- May alter results of testing for antidiuretic hormone, gastric acid stimulation, Doppler ultrasonography, 5-Hydroxyindoleacetic acid, T-cell counts.

RECOMMENDED MONITORING:

- Daily nicotine intake
- Craving and withdrawal symptoms

OUTCOMES MEASURES:

Therapeutic:

- Abstinence
- Reduction in craving
- Lack of withdrawal symptoms

Safety/Adverse Effect:

- Gastrointestinal symptoms
- Oral discomfort
- Cardiac symptoms

REFERENCES:

1. Choi JH, Dresler CM, Norton MR, Strbas KR. Pharmacokinetics of the nicotine polacrilex lozenge. *Nic Tob Res* 2003;5(5):635-644.
2. Shiffman S, Dresler CM, Hajek P, et al. Efficacy of the nicotine lozenge for smoking cessation. *Arch Intern Med* 2002;162:1267-1276.
3. Silagy C, Lancaster T, Stead L, Mant D, Fowler G. Nicotine replacement therapy for smoking cessation (Cochrane review). IN: the Cochrane Library, Issue 3, 2004. Chichester, UK: John Wiley & Sons, Ltd.
4. Wallstrom M, sand L, Nilsson F, Hirsch J. The long-term effect of nicotine on the oral mucosa. *Addiction* 1999;94(3):417-423.
5. Nicotine & Nicotine polacrilex, AFHS Drug Information 2004.
6. Nicotine, Micromedex DRUGDEX and PDR.
7. Clinical Practice Guideline: Treating Tobacco Use and Dependence, U.S. Department of Health and Human Services, pages 77-78
(http://www.surgeongeneral.gov/tobacco/treating_tobacco_use.pdf)
8. http://www.oqp.med.va.gov/cpg/TUC/TUC_Base.htm