

2018-12-07



Throat Lozenges Monograph

Health Products and Food Branch

FOREWORD

This monograph is intended to replace the existing Throat lozenges Monograph of January 13, 1995. This monograph describes the requirements necessary to receive market authorization [i.e. a Drug Identification Number (DIN) or a Natural Product Number (NPN)], for throat lozenges products. The monograph identifies the permitted medicinal and non-medicinal ingredients, concentrations, indications, directions and conditions of use for these products to be market authorized without the submission to Health Canada of additional evidence. It also may contain the test methods recommended to be used to comply with the requirements of this monograph. Products which do not meet the criteria outlined in this document can apply for market authorization outside of the monograph stream.

Applicants are reminded that throat lozenges products, like other non-prescription drugs or natural health products, are subject to the Food and Drug Regulations or the Natural Health Products Regulations administered by the Natural and Non-prescription Health Products Directorate (NNHPD). This includes requirements related to labelling, manufacturing and product specifications. Additional information on labels, outside of those specified in the monograph, such as additional directions for use and/or non-therapeutic claims are acceptable as long as they meet the [Guidelines for the Nonprescription and Cosmetic Industry Regarding Non-therapeutic Advertising and Labelling Claims](#), the [Guidelines for Consumer Advertising of Health products for Nonprescription drugs, Natural Health Products, Vaccines and Medical Devices](#), and are not false, misleading or counterintuitive to the use of the product.

The development of this monograph is the result of a thorough review of existing regulations, guidance documents, policies and current practices within Health Canada and other leading regulatory agencies.

Note:

The solidus (/) indicates that the terms and/or the statements are synonymous. Either term or statement may be selected by the applicant. Text in parentheses is additional optional information which can be included on the Product Licence Application form and label at the applicant's discretion.

MEDICINAL INGREDIENT(S)

Throat lozenges products are classified as natural health products (NHPs) if they contain only ingredients from Table 1, 2 and 3. Applicants applying for an NPN can access the appropriate forms and guidance at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription.html>.

Throat lozenges products are classified as non-prescription drugs if they contain at least one ingredient from Table 4 and 5. Applicants applying for a DIN can access the appropriate forms and guidance at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents.html>

Table 1: NHP medicinal ingredients (analgesic/anaesthetic)

Proper name(s)	Common name(s)	Source material(s)	Quantity per lozenge
		Common name(s)	
alpha-Hydroxytoluene	Benzyl alcohol	Benzyl alcohol	100 – 500 mg
4-Aminobenzoic acid, ethyl ester	Benzocaine	Para-aminobenzoic acid	2 – 15 mg
2-Hydroxybenzenemethanol	Salicyl alcohol	Salicyl alcohol	50 – 100 mg
<ul style="list-style-type: none"> • (1R,2S,5R)-rel-5-methyl-2-(1-methylethyl)-cyclohexanol • (1RS,2RS,5RS)-(±)-5-Methyl-2-(1-methylethyl)cyclohexanol • dl-Menthol 	<ul style="list-style-type: none"> • dl-Menthol • Racemic Menthol 	dl-Menthol	2 – 20 mg
<ul style="list-style-type: none"> • (1R,2S,5R)-5-methyl-2-(propan-2-yl)cyclohexan-1-ol • (1R,2S,5R)-5-methyl-2-(propan-2-yl)cyclohexan-1-ol • l-Menthol 	<ul style="list-style-type: none"> • l-Menthol • Menthol 	l-Menthol	2 – 20 mg
Phenol	Phenol	Phenol	10 – 50 mg

Table 2: NHP medicinal ingredients (demulcent)

Proper name(s)	Common name(s)	Source material(s)			Quantity per lozenge
		Proper name(s)	Common name(s)	Part(s)	
Gelatin	<ul style="list-style-type: none"> • Gelatin • Partially hydrolyzed collagen 	N/A	Gelatin	N/A	≤100%
Pectin	Pectin	N/A	Pectin	N/A	≤100%
<i>Ulmus rubra</i>	<ul style="list-style-type: none"> • Slippery elm • Red elm 	<i>Ulmus rubra</i>	N/A	Stem bark inner	10 - 15%

Table 3: NHP Complementary medicinal ingredient (safety only)¹

Proper name(s)	Common name(s)	Source material(s)	Quantity per
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		Proper name(s)	Part(s)	lozenge
<i>Eucalyptus globulus</i>	<ul style="list-style-type: none"> • Eucalyptus essential oil • Eucalyptus globulus leaf essential oil 	Eucalyptus globulus	Leaf	0.2 – 15 mg

1. See permitted combinations.

Table 4: Non-prescription drug medicinal ingredients (analgesic/anaesthetic)

Proper name(s)	Common name(s)	Source material(s)	Quantity per lozenge
		Common name(s)	
4-n-Butoxy-beta-(1-piperidyl)propiofenone hydrochloride	Dyclonine hydrochloride	Dyclonine hydrochloride	1 – 3 mg
<ul style="list-style-type: none"> • 4-Hexyl-1,3-benzenediol • 4-Hexylresorcinol 	Hexylresorcinol	Hexylresorcinol	2 – 4 mg

Table 5: Non-prescription drug medicinal ingredients (antiseptic)

Proper name(s)	Common name(s)	Source material(s)	Quantity per lozenge
		Common name(s)	
1-Hexadecylpyridinium chloride	Cetylpyridinium chloride (antiseptic)	Cetylpyridinium chloride	1 – 2 mg
<ul style="list-style-type: none"> • 1,1'-(1,10-Decanediyl)bis-(4-amino-2-methylquinolinium chloride) • 1,1'-Decamethylenebis(4-aminoquinaldinium chloride) 	Dequalinium chloride (antiseptic)	Dequalinium chloride	0.25 mg
<ul style="list-style-type: none"> • Dodecyldimethyl(2-phenoxyethyl)ammonium bromide • N,N-Dimethyl-N-(2-phenoxyethyl)-1-dodecanaminium bromide 	Domiphen bromide (antiseptic)	Domiphen bromide	1.5 mg
<ul style="list-style-type: none"> • 4-Hexyl-1,3-benzenediol • 4-Hexylresorcinol 	Hexylresorcinol (analgesic/anaesthetic/antiseptic)	Hexylresorcinol	2 – 4 mg

ROUTE(S) OF ADMINISTRATION

Oral

DOSAGE FORM(S)

Lozenges

USE(S) OR PURPOSE(S)

Self-Care Framework Category I Uses or Purposes:

For all products:

- For the temporary relief of (minor) sore throat.

For products containing menthol, phenol, hexylresorcinol, benzocaine, dyclonine hydrochloride, benzyl alcohol, salicyl alcohol:

- For temporary relief of pain of (minor) sore throat.

For products containing slippery elm bark powder, gelatin, or pectin:

- For the protection of irritated area in throat.

For products containing menthol with a concentration of 1 – 20 mg:

- Helps ease/relieve nasal congestion
- Makes nasal passages feel clearer

For products containing menthol with a concentration of 5 – 20 mg:

- For the temporary relief of coughs

For products containing hexylresorcinol, cetylpyridinium chloride, domiphen bromide, phenol, or dequalinium chloride:

- Antiseptic

DOSE(S)

Subpopulation(s):

Children 6 to 11 years, Adolescents 12 to 17 years, Adults 18 years and older

Quantity:

See Tables 1, 2, 3, 4 and 5 above.

Permitted combinations:

The concentration of the individual ingredients must not exceed the maximum value permitted as single medicinal ingredients, as listed in Table 1, 2, 3, and 4 above.

- menthol + eucalyptus oil
- menthol + hexylresorcinol
- benzocaine + cetylpyridinium chloride
- benzocaine + menthol
- benzocaine + phenol
- any demulcent+ any anaesthetic/analgesic
- any demulcent + any antiseptic

Directions for use:

For products containing menthol, eucalyptus oil, gelatin or pectin:

- Dissolve one lozenge slowly in the mouth as required.

For products containing phenol:

- Dissolve one lozenge slowly in the mouth every 2 hours as needed to a maximum daily dose of 300 mg [as expressed in number of lozenges]

For products containing hexylresorcinol, benzyl alcohol, dyclonine hydrochloride, cetylpyridinium chloride, domiphen bromide, dequalinium or salicyl alcohol:

- Dissolve one lozenge slowly in the mouth every 2 hours as needed

For products containing slippery elm bark powder:

- Dissolve one lozenge slowly in the mouth every 1 - 2 hours up to a maximum of 6 g per day [as expressed in number of lozenges]

For products containing benzocaine:

- Dissolve one lozenge slowly in the mouth. Do not bite, chew or swallow whole. May be repeated every two hours as needed up to a maximum of 3 mg/kg body weight per day [as expressed in number of lozenges] (USP DI 2006; US FDA 1991).
- Avoid eating or drinking while numbness persists.
- Children under 12 years of age should be supervised by an adult in the use of this product.

Duration(s) of use:

For products containing benzocaine:

- For occasional use only

RISK INFORMATION

Caution(s) and warning(s):

For all products:

- **Keep out of reach of children.** In case of overdose, call a poison control centre or get medical help right away.

For products including claim for the temporary relief of (minor) sore throat and/or temporary relief of pain of (minor) sore throat:

- **Stop use and ask/ consult a doctor/ physician/ health care practitioner/ health care provider/ health care professional if** sore throat symptoms worsen or persist for more than 2 days

For products including claim for the temporary relief of coughs:

- **Stop use and ask/ consult a doctor/ physician/ health care practitioner/ health care provider/ health care professional if** cough worsens and persists for more than 7 days, or is accompanied by a fever.

For products containing ingredients in Tables 4 or 5:

- **Ask/ Consult a doctor or pharmacist/ physician or pharmacist/ health care practitioner/ health care provider/ health care professional before use if you are** pregnant or breastfeeding.

For products containing benzocaine:

- **Stop use and ask/ consult a doctor/ physician/ health care practitioner/ health care provider/ health care professional if** sore throat is severe, persists for more than two days, or is accompanied by or followed by other symptoms such as fever, headache, rash, swelling, nausea, or vomiting (Pray 2006; USP DI 2006; US FDA 1991).

Contraindication(s):

For products containing benzocaine:

- **Do not use** if allergic to benzocaine.

Known adverse reaction(s):

For products containing benzocaine:

- **Allergy alert** Hypersensitivity/allergy is known to occur. In such a case, discontinue use / **Allergy alert** Stop use if hypersensitivity/allergy occurs (HC 2011a;b US FDA 1991).

NON-MEDICINAL INGREDIENTS

Ingredients must be chosen from the current [Natural Health Products Ingredients Database](#) (NHPID) and must meet the limitations outlined in that database, the Food and Drug Regulations (FDR), and the current [Cosmetic Ingredient Hotlist](#), when relevant.

STORAGE CONDITION(S)

No statement required.

SPECIFICATIONS

This monograph describes those requirements that are specific to this class of non-prescription drugs and to natural health products (NHPs). Any change to the manufacturing process that impacts the safety and efficacy of the ingredients, such as the use of novel technology (e.g. nanotechnology), requires supporting data and will be reviewed outside the monograph.

For products containing Table 1, 2 and 3 NHP medicinal ingredients only:

The finished product specifications must be established in accordance with the requirements described in the NNHPD [Quality of Natural Health Products Guide](#). The medicinal ingredient must comply with the requirements outlined in the [NHPID](#).

For products containing Table 4 and 5 non-prescription drug medicinal ingredients:

Requirements described in the Regulations to the Food and Drugs Act must be met.

DRUG FACTS TABLES (Format Optional for Self-Care Category I)

Drug Facts	
Active ingredient (w/w) Cetylpyridinium chloride XX mg	Purpose Antiseptic throat lozenge
Uses • For the temporary relief of (minor) sore throat • Antiseptic	
Warnings Ask/ Consult a doctor or pharmacist/ physician or pharmacist/ health care practitioner/ health care provider/ health care professional before use if you are pregnant or breastfeeding	
Stop use and ask/ consult a doctor/ physician/ health care practitioner/ health care provider/ health care professional if sore throat symptoms worsen or persist for more than 2 days	
Keep out of reach of children. In case of overdose, call a poison control centre or get medical help right away.	
Directions Adults and children 6 years and older: • Dissolve one lozenge slowly in the mouth every 2 hours as needed	
Other information [If no other information, delete this section]	
Inactive ingredients List NMI's	
Questions? 1-XXX-XXX-XXXX (or other contact information)	

Drug Facts	
Active ingredient (w/w) Dequalinium chloride XX mg	Purpose Antiseptic throat lozenge
Uses • For the temporary relief of (minor) sore throat • Antiseptic	
Warnings Ask/ Consult a doctor or pharmacist/ physician or pharmacist/ health care practitioner/ health care provider/ health care professional before use if you are pregnant or breastfeeding	
Stop use and ask/ consult a doctor/ physician/ health care practitioner/ health care provider/ health care professional if sore throat symptoms worsen or persist for more than 2 days	
Keep out of reach of children. In case of overdose, call a poison control centre or get medical help right away.	
Directions Adults and children 6 years and older: • Dissolve one lozenge slowly in the mouth every 2 hours as needed	
Other information [If no other information, delete this section]	
Inactive ingredients List NMIs	
Questions? 1-XXX-XXX-XXXX (or other contact information)	

Drug Facts	
Active ingredient (w/w) Domiphen bromide XX mg	Purpose Antiseptic throat lozenge
Uses • For the temporary relief of (minor) sore throat • Antiseptic	
Warnings Ask/ Consult a doctor or pharmacist/ physician or pharmacist/ health care practitioner/ health care provider/ health care professional before use if you are pregnant or breastfeeding	
Stop use and ask/ consult a doctor/ physician/ health care practitioner/ health care provider/ health care professional if sore throat symptoms worsen or persist for more than 2 days	
Keep out of reach of children. In case of overdose, call a poison control centre or get medical help right away.	
Directions Adults and children 6 years and older: • Dissolve one lozenge slowly in the mouth every 2 hours as needed	
Other information [If no other information, delete this section]	
Inactive ingredients List NMIs	
Questions? 1-XXX-XXX-XXXX (or other contact information)	

Drug Facts	
Active ingredient (w/w) Dyclonine hydrochloride XX mg	PurposeThroat lozenge
Uses • For the temporary relief of (minor) sore throat • For temporary relief of pain of (minor) sore throat	
Warnings Ask/ Consult a doctor or pharmacist/ physician or pharmacist/ health care practitioner/ health care provider/ health care professional before use if you are pregnant or breastfeeding	
Stop use and ask/ consult a doctor/ physician/ health care practitioner/ health care provider/ health care professional if sore throat symptoms worsen or persist for more than 2 days	
Keep out of reach of children. In case of overdose, call a poison control centre or get medical help right away.	
Directions Adults and children 6 years and older: • Dissolve one lozenge slowly in the mouth every 2 hours as needed	
Other information [If no other information, delete this section]	
Inactive ingredients List NMIs	
Questions? 1-XXX-XXX-XXXX (or other contact information)	

Drug Facts	
Active ingredient (w/w) Hexylresorcinol XX mg	Purpose Antiseptic throat lozenge
Uses • For the temporary relief of (minor) sore throat • For temporary relief of pain of (minor) sore throat • Antiseptic	
Warnings Ask/ Consult a doctor or pharmacist/ physician or pharmacist/ health care practitioner/ health care provider/ health care professional before use if you are pregnant or breastfeeding	
Stop use and ask/ consult a doctor/ physician/ health care practitioner/ health care provider/ health care professional if sore throat symptoms worsen or persist for more than 2 days	
Keep out of reach of children. In case of overdose, call a poison control centre or get medical help right away.	
Directions Adults and children 6 years and older: • Dissolve one lozenge slowly in the mouth every 2 hours as needed	
Other information [If no other information, delete this section]	
Inactive ingredients List NMIs	
Questions? 1-XXX-XXX-XXXX (or other contact information)	

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