Throat Lozenges

Throat Lozenges Monograph Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 104 KB) Date 2024-11-29 Foreword This monograph is intended to replace the existing Throat lozenges Monograph of December 7, 2018. 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. Notes Text in parentheses is additional optional information which can be included on the label at the applicant's discretion. The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant on the label. Medicinal Ingredients 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 (NPDs) 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 Proper name(s), Common name(s), Source information Table 1: NHPs: Medicinal ingredients analgesic/anaesthetic Proper name(s) Common name(s) Source information Source ingredient(s) Source material(s) Part(s) alpha-Hydroxytoluene Benzyl alcohol Benzyl alcohol N/A N/A 4-Aminobenzoic acid, ethyl ester Benzocaine Benzocaine N/A N/A 2-Hydroxybenzenemethanol Salicyl alcohol Salicyl alcohol N/A N/A (1R,2S,5R)-rel-5-Methyl-2-(1-methylethyl)-cyclohexanol (1RS,2RS,5RS)-(±)-5-Methyl-2-(1-methylethyl)cyclohexanol dl-Menthol dl-Menthol Racemic Menthol dl-Menthol N/A N/A (1R,2S,5R)-5-Methyl-2-(1-methylethyl)cyclohexanol (1R,2S,5R)-5-Methyl-2-(propan-2-yl)cyclohexan-1-ol l-Menthol l-Menthol Menthol l-Menthol N/A N/A N/A Mentha arvensis Herb top flowering Herb top Leaf N/A Mentha canadensis Herb top N/A Mentha x piperita Herb top flowering Leaf Phenol Phenol Phenol N/A N/A Table 2: NHPs: Medicinal ingredients demulcent Proper name(s) Common name(s) Source information Source ingredient(s) Source material(s) Part(s) Gelatin Gelatin Partially hydrolyzed collagen Gelatin N/A N/A Pectin Pectin N/A Citrus aurantiifolia Fruit flesh Fruit peel Fruit peel inner Fruit peel outer Citrus limon Fruit Fruit peel Citrus maxima Fruit Citrus paradisi Fruit Fruit peel Citrus reticulata Fruit Citrus sinensis Fruit Fruit peel Malus domestica Fruit Ulmus rubra Red elm Slippery elm N/A Ulmus rubra Stem bark inner 1 1 Preparation : Dry. Table 3: NHPs: Complementary medicinal ingredient (safety only) 1 Proper name(s) Common name(s) Source information Source material(s) Part(s) Eucalyptus globulus Eucalyptus essential oil Eucalyptus globulus leaf essential oil Eucalyptus globulus Leaf 1 See permitted combinations. Table 4: NPDs: Medicinal ingredients analgesic/anaesthetic Proper name(s) Common name(s) Quantity per lozenge 4-n-Butoxy-beta-(1-piperidyl)propiophenone hydrochloride Dyclonine hydrochloride 1-3

mg 4-Hexyl-1,3-benzenediol 4-Hexylresorcinol Hexylresorcinol 2-4 mg Table 5: NPDs: Medicinal ingredients antiseptic Proper name(s) Common name(s) Quantity per lozenge 1-Hexadecylpyridinium chloride Cetylpyridinium chloride(antiseptic) 1-2 mg 1,1'-(1,10-Decanediyl)bis-(4-amino-2-methylquinolinium chloride) 1,1'-Decamethylenebis(4-aminoquinaldinium chloride) Dequalinium chloride (antiseptic) 0.25 mg Dodecyldimethyl(2-phenoxyethyl)ammonium bromide N,N-Dimethyl-N-(2-phenoxyethyl)-1-dodecanaminium bromide Domiphen bromide(antiseptic) 1.5 mg 4-Hexyl-1,3-benzenediol 4-Hexylresorcinol Hexylresorcinol (analgesic/anesthetic/antiseptic) 2-4 mg Route of administration Oral Dosage form(s) Lozenge Use(s) or Purpose(s) Self-Care Framework Category I Uses or Purposes: All products For temporary relief of (minor) sore throat. Temporarily relieves/soothes (minor) sore throat. Products containing dl-menthol/l-menthol, phenol, hexylresorcinol, benzocaine, dyclonine hydrochloride, benzyl alcohol, salicyl alcohol For temporary relief of pain of (minor) sore throat. Temporarily relieves/soothes pain of (minor) sore throat. Products containing slippery elm, gelatin, or pectin For (the) protection of irritated area in the throat. Protects irritated areas in the throat. Products containing 2 - 20 mg of dl-menthol and/or l-menthol Helps ease/relieve nasal congestion Makes nasal passages feel clearer Products containing 5 - 20 mg of dl-menthol and/or l-menthol For (the) temporary relief of coughs. Temporarily relieves/soothes coughs. 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 Natural health products Table 6: NHPs: Quantity of the medicinal ingredients including daily frequency Medicinal ingredients Methods of preparation Quantity per lozenge Maximum quantity/day Maximum frequency/day Benzyl alcohol N/A 100 - 500 mg N/A up to 8 times Benzocaine N/A 2 - 15 mg N/A up to 6 times Salicyl alcohol N/A 50 - 100 mg N/A up to 8 times dl-Menthol and/or l-Menthol N/A 2 - 20 mg N/A up to 16 times Phenol N/A 10 - 50 mg 300 mg up to 8 times Gelatin N/A 2 - 100% N/A up to 16 times Pectin N/A 2 - 100% N/A up to 16 times Slippery elm Powdered* 200 - 300 mg 6 g up to 16 times Eucalyptus essential oil Oil, Essential (water steam distillation) 0.2 - 15 mg N/A up to 16 times *Note: The method of preparation 'powdered' is defined as a dried and ground preparation (= unextracted). Non-prescription drugs See tables 4 and 5 above for NPD quantities per lozenge. Permitted combinations: The concentration of each medicinal ingredient per lozenge must not exceed its maximum value as listed in Tables 4, 5 and 6 above (e.g., 20 mg total dl-menthol/l-menthol + 15 mg eucalyptus essential oil). dl-menthol/l-menthol + eucalyptus essential oil dl-menthol/l-menthol + hexylresorcinol benzocaine + cetylpyridinium chloride benzocaine + dl-menthol/l-menthol benzocaine + phenol 1 demulcent+ 1 anaesthetic/analgesic 1 demulcent + 1 antiseptic Directions for use Products containing dl-menthol/l-menthol, eucalyptus essential oil, gelatin, pectin or slippery elm Dissolve 1 lozenge slowly in the mouth as needed. Products containing hexylresorcinol, benzyl alcohol, dyclonine hydrochloride, cetylpyridinium chloride, domiphen bromide, dequalinium, salicyl alcohol or phenol Dissolve 1 lozenge slowly in the mouth every 2 hours as needed. Products containing benzocaine Allow product to dissolve slowly in the mouth. Do not bite, chew or swallow whole. May be repeated every 2 hours as needed (or as directed by a health care practitioner/health care provider/health care professional/doctor/physician) (USP DI 2006; US FDA 1994). Use the smallest amount possible to achieve desired result. Children under 12 years of age should be supervised by an adult in the use of this product (US FDA 1994). Duration(s) of Use Products containing benzocaine For occasional use only. Risk Information Caution(s) and warning(s) All products Keep out of reach of children. In case of overdose, call a poison control centre or get medical help right away. Products including claim for the temporary relief of (minor) sore throat and/or temporary relief of pain of (minor) sore throat and/or irritated throat (except for products containing benzocaine) Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if sore throat worsens or persists for more than 2 days. Products including claim for the temporary relief of coughs Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if cough worsens and persists for more than 7 days, or is accompanied by a fever. Products containing ingredients in Tables 4 or 5 Ask a doctor/physician/health care practitioner/health care provider/health care professional before use if you are pregnant or breastfeeding. Products containing benzocaine When using this product do not chew gum or food while numbness persists (USP DI 2006; CPhA 1996). Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if sore throat is severe, persists for more than 2 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 1994). Contraindication(s) Products containing benzocaine Do not use if you are allergic to benzocaine. Known adverse reaction(s) Products containing benzocaine Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if the following symptoms appear: weakness, confusion, headache, difficulty breathing and/or pale, gray or blue coloured skin. These symptoms may be signs of methemoglobinemia, a rare disorder, which may appear up to 2 hours after use (US FDA 2018; US FDA 2011a,b; HC 2006). Stop use if hypersensitivity/allergy occurs (US FDA 1994). 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 conditions Must be established in accordance with the requirements described in the Natural Health Products Regulations or the Food and Drug Regulations . Specifications This monograph describes those requirements that are specific to this class of non-prescription drugs and to natural health products. 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 NPD medicinal ingredients: Requirements described in the Regulations to the Food and Drugs Act must be met. For products containing Table 1, 2 and 3 NHP medicinal ingredients only: EXAMPLES OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details. For products containing Table 4 and 5 NPD medicinal ingredients: DRUG FACTS TABLES (Format Optional for Self-Care Category I) References Compendium of therapeutics for minor ailments (CTMA). Power B et al., editors. Canadian Pharmacists Association ; 2016 Compendium of products for minor ailments (CPMA). Power B, et al., editors. Canadian Pharmacists Association ; 2016 CPhA 1996: Carruthers-Czyzewski P, Gillis C, Letwin D, editors. Nonprescription Drug Reference for Health Professionals. Ottawa (ON): Canadian Pharmaceutical Association; 1996. 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Available from: https://www.federalregister.gov/documents/1994/02/09/94-2262/oral-health-care-drug-products-for-over-the-counter-human-use-tentative-final-monograph-for-oral USP DI 2006: Drug Information for the Health Care Professional. 26th edition, Volume 1. Greenwood Village (CO): Thomson Micromedex; 2006. Report a problem on this page Date modified: 2019-03-01

RISK INFORMATION

Caution(s) and warning(s) All products Keep out of reach of children. In case of overdose, call a poison control centre or get medical help right away. Products including claim for the temporary relief of (minor) sore throat and/or temporary relief of pain of (minor) sore throat and/or irritated throat (except for products containing benzocaine) Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if sore throat worsens or persists for more than 2 days. Products including claim for the temporary relief of coughs Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if cough worsens and persists for more than 7 days, or is accompanied by a fever. Products containing ingredients in Tables 4 or 5 Ask a doctor/physician/health care practitioner/health care provider/health care professional before use if you are pregnant or breastfeeding. Products containing benzocaine When using this product do not chew gum or food while numbness persists (USP DI 2006; CPhA 1996).Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if sore throat is severe, persists for more than 2 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 1994). Contraindication(s) Products containing benzocaine Do not use if you are allergic to benzocaine. Known adverse reaction(s) Products containing benzocaine Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if the following symptoms appear: weakness, confusion, headache, difficulty breathing and/or pale, gray or blue coloured skin. These symptoms may be signs of methemoglobinemia, a rare disorder, which may appear up to 2 hours after use (US FDA 2018; US FDA 2011a,b; HC 2006).Stop use if hypersensitivity/allergy occurs (US FDA 1994).

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in theNatural Health Products Regulations or the Food and Drug Regulations.

SPECIFICATIONS

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

REFERENCES

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Proper name(s)	Common name(s)	Source information		
Source ingredient(s)	Source material(s)	Part(s)		
alpha-Hydroxytoluene	Benzyl alcohol	Benzyl alcohol	N/A	N/A
4-Aminobenzoic acid, ethyl ester	Benzocaine	Benzocaine	N/A	N/A
2-Hydroxybenzenemethanol	Salicyl alcohol	Salicyl alcohol	N/A	N/A
(1R,2S,5R)-rel-5-Methyl-2-(1-methylethyl)-cyclohexanol	dl-Menthol(1RS,2RS,5RS)-(±)-5-Methyl-2-(1-methylethyl)cyclohexanol	dl-Menthol	N/A	N/A
(1R,2S,5R)-5-Methyl-2-(1-methylethyl)cyclohexanol	l-Menthol(1RVS,5R)-5-Methyl-2-(propan-2-yl)cyclohexan-1-oll-Menthol	l-Menthol	N/A	N/A
N/A	Mentha arvensis	Herb top floweringHerb topLeaf		
N/A	Mentha canadensis	Herb top		
N/A	Mentha x piperita	Herb top floweringLeaf		
Phenol	Phenol	Phenol	N/A	N/A

s)	Common name(s)	Source information		
	GelatinPartially hydrolyzed collagen	Gelatin	N/A	N/A
	Pectin	N/A	Citrus aurantiifolia	Fruit fleshFruit peelFrui
	FruitFruit peel			
	Fruit			

	FruitFruit peel			
	Fruit			
	FruitFruit peel			
	Fruit			
	Red elmSlippery elm	N/A	Ulmus rubra	Stem bark inner1

Proper name(s)	Common name(s)	Source information	
Source material(s)	Part(s)		
Eucalyptus globulus	Eucalyptus essential oilEucalyptus globulus leaf essential oil	Eucalyptus globulus	Leaf

Proper name(s)	Common name(s)	Quantity per lozenge
4-n-Butoxy-beta-(1-piperidyl)propiophenone hydrochloride	Dyclonine hydrochloride	1-3 mg
4-Hexyl-1,3-benzenediol4-Hexylresorcinol	Hexylresorcinol	2-4 mg

Proper name(s)	Common name(s)	Quantity per lozenge
1-Hexadecylpyridinium chloride	Cetylpyridinium chloride(antiseptic)	1-2 mg
1,1'-(1,10-Decanediyl)bis-(4-amino-2-methylquinaldinium chloride)	Dequalinium chloride(1,1'-Decamethylenebis(4-amino-2-methylquinaldinium chloride)	0.25 mg
Dodecyldimethyl(2-phenoxyethyl)ammonium bromide	Domiphen bromide(N,N-Dimethyl-N-(2-phenoxyethyl)-1-dodecanaminium bromide	0.5 mg
4-Hexyl-1,3-benzenediol4-Hexylresorcinol	Hexylresorcinol (analgesic/anesthetic/antiseptic)	2-4 mg

nts	Methods of preparation	Quantity per lozenge	Maximum quantity/day	Maximum f
	N/A	100 - 500 mg	N/A	up to 8 times
	N/A	2 - 15 mg	N/A	up to 6 times
	N/A	50 - 100 mg	N/A	up to 8 times
enthol	N/A	2 - 20 mg	N/A	up to 16 time
	N/A	10 - 50 mg	300 mg	up to 8 times
	N/A	2 - 100%	N/A	up to 16 time
	N/A	2 - 100%	N/A	up to 16 time
	Powdered*	200 - 300 mg	6 g	up to 16 time
oil	Oil, Essential (water steam distillation)	0.2 - 15 mg	N/A	up to 16 time