Health Canada Santé Canada

NATURAL HEALTH PRODUCT

HOMEOPATHY

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredients.

Notes

- By submitting a PLA referencing this monograph, the applicant is attesting that the product will comply fully with the recommended conditions of use outlined in this monograph. The conditions of use include methods of preparations, source materials, doses, durations of use, combinations of medicinal ingredients, and risk statements.
- Text in parentheses is additional optional information which can be included on the PLA and product 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.

Date August 5, 2019

Proper name(s), Common name(s), Source material(s)

Notes

- The proper name(s), common name(s) and source material(s) must be as per the homeopathic monograph referenced as the Standard or Grade (please refer to the specifications).
- The medicinal ingredient(s) must be a permitted substance with a homeopathic monograph in one of the Natural and Non-Prescription Health Products Directorate (NNHPD) accepted homeopathic pharmacopoeias[1,2,3,4,5].
- Medicinal ingredients considered imponderables are not included within the scope of this monograph.

Route(s) of administration

The acceptable route(s) of administration must be acceptable as per the NNHPD *Evidence for Homeopathic Medicines* guidance document.

Dosage form(s)

The acceptable pharmaceutical dosage forms include, but are not limited to those indicated in Table 1 below.

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Use(s) or Purpose(s)

Homeopathic preparation/remedy/medicine.

Dose(s)

Subpopulation(s)

As specified below.

Quantity(ies)

Table 1. Dosage forms and their recommended dose for each subpopulation

Dosage Form(s)	Subpopulation(s)	General dosing		Maximum Acute Dosing (Optional)
		Maximum Dosing	Maximum Frequency	
Globules (small pellets, pills) (Oral)	Adolescents 12-17 years and Adults 18 years and older	1 whole unit dose (tube or container)	1 time per day	10-20 granules, 2-3 times per day
	Children 1-11 years*			
	Infants 0-11 months*			
Granules (regular or large pellets)	Adolescents 12-17 years and Adults 18 years and older	3-5 granules	2-3 times per day	Every 15-60 minutes (not to exceed 12 times per day) or until improvement of symptoms. Then resume general dosing.
	Children 1-11 years*			
	Infants 0-11 months*			
Tablets	Adolescents 12-17 years and Adults 18 years and older	1-4 tablets	1-4 times per day	Every 15-60 minutes (not to exceed 12 times per day) or until improvement of symptoms. Then resume general dosing.
	Children 6-11 years	1-3 tablets	1-4 times per day	
	Children 1-5 years*	½-3 tablets	1-3 times per day	
	Infants 0-11 months*	½-3 tablets	1-2 times per day	
Oral Drops	Adolescents 12-17 years and Adults 18 years and older	10-30 drops	1-3 times per day	Every 15-60 minutes (not to exceed 12 times per day) or until improvement of symptoms. Then resume general dosing.
	Children 6-11 years	5-15 drops		
	Children 1-5 years	5-10 drops		
	Infants 0-11 months	1-5 drops		

Liquid (Oral drinkable vials)	Adolescents 12-17 years and Adults 18 years and older	1 ampoule	1-3 times per day	Not to exceed 3 times per day
	Children 6-11 years	2/3 ampoule		
	Children 1-5 years	½ ampoule		
	Infants 0-11 months	1/3 ampoule		
Oral solution (Unit dose)	Adolescents 12-17 years and Adults 18 years and older	Unit oral dose	1-3 times per day	Give one unit dose upon onset of symptoms. Repeat two more times at 15-minute intervals. Repeat process up to 9 times per day if symptoms reappear.
	Children 1-11 years			
	Infants 0-11 months			
Oral Syrup	Adolescents 12-17 years and Adults 18 years and older	1-2 tsp	Every 4 to 6 hours	N/A
	Children 1-11 years	½-1 tsp	1-3 times per day	
	Infants 0-11 months	½ tsp	1-3 times per day	
Cream or Ointment	Infants 0-11 months, Children 1-11 years, Adolescents 12-17 and Adults 18 years and older	Cover affected area	Use as needed	N/A
Nasal spray	Adolescents 12-17 years and Adults 18 years and older	1-2 sprays/ nostril	3-5 times per day	N/A
	Children 1-11 years	1 spray/nostril	4 times per day	
	Infants 0-11 months	1 spray/nostril	4 times per day	
Eye Drops	Adolescents 12-17 years and Adults 18 years and older	2-3 drops	3 times per day	1 drop in the affected eye every 15 minutes for a maximum of 3 hours.
	Children 1-11 years	1-2 drops	3 times per day	
	Infants 0-11 months	1 drop	2 times per day	
Ear Drops	Adolescents 12-17 years and Adults 18 years and older	1 complete vial	3 times per day	Every 15-60 minutes (not to exceed 12 times per day) or until improvement of symptoms. Then resume general dosage.
	Children 1-11 years	3-4 drops		
	Infants 0-11 months	2-3 drops		

Suppositories	Adolescents 12-17 years and Adults 18 years and older	1 suppository	1-4 times per day	Maximum 5 times per day
	Children 6-11 years		1-3 times per day	Maximum 4 times per day
	Children 1-5 years		1-2 times per day	Maximum 3 times per day
	Infants 0-11 months		1-2 times per day	Maximum 2 times per day

*****Dissolve dose in a small amount of water before administration to infants and children 0-5 years old.

Potency

The homeopathic potency of each medicinal ingredient must be at or above the minimum potency specified in the Natural Health Products Ingredients Database (NHPID).

Note
The minimum potencies indicated in the NHPID are generally based on the following unless specific safety concerns have been identified:

- The OTC limit for HPUS
- 4D for HAB
- 12 CH for pharmacopoeia other than HPUS or HAB/GHP

Method(s) of preparation

The method(s) of preparation must be as per the homeopathic monograph referenced as the Standard or Grade (please refer to the specifications). It is also acceptable to use another method from an NNHPD accepted homeopathic pharmacopoeia not referenced as the Standard or Grade. In this case, the selected method of preparation must be appropriate for the medicinal ingredient.

Direction(s) for use

Use as directed by a health care practitioner/health care provider/health care professional/ doctor/physician.

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

- Consult a health care practitioner/health care provider/health care professional/doctor/ physician if symptoms persist or worsen.
- Consult a health care practitioner/health care provider/health care professional/doctor/ physician prior to use if you are pregnant or breastfeeding.
- Ingredient specific risk statements when required by NHPID.

Contraindication(s)

No statement required.

Known adverse reaction(s)

No statement required.

Non-medicinal ingredients

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

Storage conditions

No statement required.

Specifications

- The finished product must comply with the requirements outlined in the current NNHPD *Evidence for Homeopathic Medicines* guidance document.
- The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- The medicinal ingredient(s) must comply with the requirements outlined in the NHPID.
- All medicinal ingredients of animal origin must be sterilized as per HPUS and HAB requirements or equivalent.
- If the method of preparation includes the use of natural lactose for trituration, an Animal Tissue form for lactose must be submitted.

Standard or Grade

Must reference a homeopathic monograph in one of the most recent versions of NNHPD accepted homeopathic pharmacopoeias: HPUS[1], HAB/GHP[2], PhF[3], Ph.Eur.[4], EHP[5].

[1] *Homeopathic Pharmacopeia of the United States* (HPUS)
[2] *Homöopathisches ArzneiBuch* (HAB) or *German Homeopathic Pharmacopoeia* (GHP)
[3] *Pharmacopée française* or *French Pharmacopoeia* (PhF)
[4] *European Pharmacopoeia* (Ph.Eur.)
[5] *Encyclopedia of Homeopathic Pharmacopoeia* (EHP)

References cited

EHP 2002: Encyclopaedia of Homeopathic Pharmacopoeia, Volume 3. New Delhi (IN): Kuldeep Jain and B.Jain, 2002.

GHP 2008: German Homeopathic Pharmacopoeia, Volume 1.Stuttgart (DE): MedPharm, 2008.
HAB 2003: Homöopathisches ArzneiBuch, Band 1. Stuttgart (DE): MedPharm, 2003.

HPUS 2004: Homeopathic Pharmacopeia of the United States, Revision Service. Pennsylvania (PA): Homeopathic Pharmacopoeia Convention of the United States, 2004.

Ph.Eur. 2011: European Pharmacopoeia, 7th edition. Strasbourg (FR): Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM), 2011.

PhF 2003: French Pharmacopoeia, 10th edition. Saint-Denis Cedex(FR) : French Agency for the Safety of Health Products , 2003.