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 the statements are synonymous. Either term or statement may be selected by the applicant.

**Date** July 16, 2015

## Proper name(s), Common name(s), and 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 is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

## Use(s) or Purpose(s)

Statement(s) to the effect of

Homeopathic preparation/remedy/medicine

OR

Homeopathic preparation/remedy/medicine for the relief of [1,2]…

[1] The use or purpose must only be for the relief of a symptom or set of symptoms. The use or purpose must not imply the prevention/risk reduction or the treatment/cure of a disease, disorder, or abnormal state. The use or purpose must be supported by a reference in Appendix I.
[2] Indications either direct or implied for the relief of cough, cold and flu (influenza) symptoms are not allowed in products indicated for children 12 years and under.

## Dose

### Subpopulation(s) and Quantity(ies)

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

| Dosage Form | Sub-Population | Maximum General Dosing | Maximum Frequency | Maximum Acute Dosing (Optional) |
|---|---|---|---|---|
| Globules (small pellets, pilules) (Oral) | Adults and children ≥ 12 years | 1 whole unit dose (tube or container) | Once per day | 10-20 granules 2-3 times per day |
| | Children 1-11 years* | | | |
| | Infants 0-11 months* | | | |
| Granules (regular and large pellets) | Adults and children ≥ 12 years | 3-5 granules | 2-3 times per day | Every 15-60 minutes (up to 12 times per day) or until improvement of symptoms. Then resume general dosing. |
| | Children 1-11 years* | | | |
| | Infants 0-11 months* | | | |
| Tablets | Adults and children ≥ 12 years | 1-4 tablets | 1-4 times per day | Every 15-60 minutes (up to 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 | Adults and children ≥ 12 years | 10-30 drops | 1-3 times per day | Every 15-60 minutes (up to 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) | Adults and children ≥ 12 years | 1 ampoule | 1-3 times per day | Up to three 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) | Adults and children ≥ 12 years | 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 | Adults and children ≥ 12 years | 1-2 tsp | Every 4 to 6 hours | Not applicable |
| | Children 1-11 years | ½-1 tsp | 1-3 times per day | |
| | Infants 0-11 months | ½ tsp | 1-3 times per day | |
| Cream/Ointment | Adults and children | Cover affected area | Use as needed | Not applicable |
| Nasal spray | Adults and children ≥ 12 years | 1-2 sprays/ nostril | 3-5 times per day | Not applicable |
| | Children 1-11 years | 1 spray/ nostril | 4 times per day | |
| | Infants 0-11 months | 1 spray/ nostril | 4 times per day | |
| Eye Drops | Adults and children ≥ 12 years | 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 | |
| | Children 0-11 months | 1 drop | 2 times per day | |
| Ear Drops | Adults and children ≥ 12 years | 1 complete vial | 3 times per day | Every 15-60 minutes (up to 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 | Adults and children ≥ 12 years | 1 suppository | 1-4 times per day | Maximum 5 per day |
| | Children 6-11 years | | 1-3 times per day | Maximum 4 per day |
| | Children 1-5 years | | 1-2 times per day | Maximum 3 per day |

| | | | | |
|---|---|---|---|---|
| | Infants 0-11 months | | 1-2 times per day | Maximum 2 per day |

* Dissolve dose in a small amount of water before administration to infants and children 0-2 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.

### Directions for use

Take as directed by a health care practitioner.

## Duration of use

No statement required.

## Risk information

### Cautions and warnings

- If symptoms persist or worsen, consult a health care practitioner.
- If you are pregnant or breastfeeding, consult a health care practitioner prior to use.
- Ingredient specific risk statements where required by NHPID.

### Contraindications

No statement required.

**Known adverse reactions**

No statement required.

## Non-medicinal Ingredients

Must be chosen from the current 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 NNHPD *Quality of Natural Health Products Guide*.
- The medicinal ingredient(s) must be chosen from the current NHPID and must comply with the requirements outlined in the database
- 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)

## Reference reviewed

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.

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## Appendix I References for Homeopathic medicines with a specific recommended use or purpose

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