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 ¹²...

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

<table>
<thead>
<tr>
<th>Dosage Form</th>
<th>Sub-Population</th>
<th>Maximum General Dosing</th>
<th>Maximum Frequency</th>
<th>Maximum Acute Dosing (Optional)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Globules (small pellets, pilules) (Oral)</td>
<td>Adults and children ≥ 12 years</td>
<td>1 whole unit dose (tube or container)</td>
<td>Once per day</td>
<td>10-20 granules 2-3 times per day</td>
</tr>
<tr>
<td></td>
<td>Children 1-11 years*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Infants 0-11 months*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Granules (regular and large pellets)</td>
<td>Adults and children ≥ 12 years</td>
<td>3-5 granules</td>
<td>2-3 times per day</td>
<td>Every 15-60 minutes (up to 12 times per day) or until improvement of symptoms. Then resume general dosing.</td>
</tr>
<tr>
<td></td>
<td>Children 1-11 years*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Infants 0-11 months*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tablets</td>
<td>Adults and children ≥ 12 years</td>
<td>1-4 tablets</td>
<td>1-4 times per day</td>
<td>Every 15-60 minutes (up to 12 times per day) or until improvement of symptoms. Then resume general dosing.</td>
</tr>
<tr>
<td></td>
<td>Children 6-11 years</td>
<td>1-3 tablets</td>
<td>1-4 times per day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Children 1-5 years*</td>
<td>½-3 tablets</td>
<td>1-3 times per day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Adults and children ≥ 12 years</td>
<td>Children 6-11 years</td>
<td>Children 1-5 years</td>
<td>Infants 0-11 months</td>
</tr>
<tr>
<td>------------------------------</td>
<td>--------------------------------</td>
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<td>-------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td><strong>Oral Drops</strong></td>
<td>10-30 drops</td>
<td>5-15 drops</td>
<td>5-10 drops</td>
<td>1-5 drops</td>
</tr>
<tr>
<td></td>
<td>3 times per day</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Every 15-60 minutes (up to 12 times per day) or until improvement of symptoms. Then resume general dosing.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Liquid (Oral drinkable vials)</strong></td>
<td>1 ampoule</td>
<td>2/3 ampoule</td>
<td>½ ampoule</td>
<td>1/3 ampoule</td>
</tr>
<tr>
<td></td>
<td>3 times per day</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Up to three times per day</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Oral solution (Unit dose)</strong></td>
<td>Unit oral dose</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>3 times per day</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>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.</td>
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</tr>
<tr>
<td><strong>Oral Syrup</strong></td>
<td>1-2 tsp</td>
<td>½-1 tsp</td>
<td>½ tsp</td>
<td></td>
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<tr>
<td></td>
<td>Every 4 to 6 hours</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Not applicable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cream/Ointment</strong></td>
<td>Cover affected area</td>
<td>Use as needed</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1-2 sprays/nostril</td>
<td>3-5 times per day</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Nasal spray</strong></td>
<td>1 spray/nostril</td>
<td>4 times per day</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4 times per day</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Eye Drops</strong></td>
<td>2-3 drops</td>
<td>1-2 drops</td>
<td>1 drop</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 times per day</td>
<td>3 times per day</td>
<td>2 times per day</td>
<td></td>
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<tr>
<td></td>
<td>1 drop in the affected eye every 15 minutes for a maximum of 3 hours.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ear Drops</strong></td>
<td>1 complete vial</td>
<td>3 times per day</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 times per day</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Every 15-60 minutes (up to 12 times per day) or until improvement of symptoms. Then resume general dosage.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Suppositories</strong></td>
<td>1 suppository</td>
<td>1-4 times per day</td>
<td>Maximum 5 per day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1-3 times per day</td>
<td>1-3 times per day</td>
<td>Maximum 4 per day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1-2 times per day</td>
<td>1-2 times per day</td>
<td>Maximum 3 per day</td>
<td></td>
</tr>
</tbody>
</table>
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: HPUS¹, HAB/GHP², PhF³, Ph.Eur.⁴, EHP⁵.

1 *Homeopathic Pharmacopeia of the United States* (HPUS)
2 *Homöopathisches ArznetBuch* (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


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


Bradford LTh. Index to Homeopathic Provings. India: Boericke et Tafel; 1901.


Tome II : Baillière et fils; 1948.
Tome III : Georg & Cie; 1948.


Fare Ch. Éléments de matière médicale homéopathique vétérinaire. France: CEDH; 1993.


Hering C. The Guiding Symptoms of our Materia Medica (10 vol.), Philadelphia (PA): Boericke et Tafel; 1890.


Sieffert G. Formulaire de thérapeutique positive (Homéopathie). Leipzig (GE): Dr. Willmar Schwabe; 1899.


