

NATURAL HEALTH PRODUCT

LITHOTHERAPY

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.
- ▶ The use of the electronic Product License Application form (ePLA) is not possible for products associated with this monograph.

Date

June 24, 2013

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

Table 1 Products may contain one or more of the following ingredients

Proper name(s)	Common name(s)	Source material(s)
Adularia	Adularia	Adularia
Apatite	Apatite	Apatite
Azurite	Azurite	Azurite
Baryte	Baryte; Barytine	Baryte
Bauxite	Bauxite	Bauxite
Betafite	Betafite	Betafite
Bornite	Bornite	Bornite
Calcite	Calcite	Calcite
Celestine	Celestine; Celestite	Celestine
Cinnabar	Cinnabar	Cinnabar
Diopside	Diopside	Diopside



Proper name(s)	Common name(s)	Source material(s)
Dolomite	Dolomite	Dolomite
Erythrite	Erythrite	Erythrite
Fluorite	Fluorite	Fluorite
Galena	Galena	Galena
Garnierite	Garnierite	Garnierite
Glaucosite	Glaucosite	Glaucosite
Granite	Granite	Granite
Graphite	Graphite	Graphite
Green jasper	Green jasper	Green jasper
Halite	Halite	Halite
Hematite	Hematite	Hematite
Iodargyrite	Iodargyrite	Iodargyrite
Lazulite	Lazulite	Lazulite
Lepidolite	Lepidolite	Lepidolite
Monazite	Monazite	Monazite
Obsidian	Obsidian	Obsidian
Orpiment	Orpiment	Orpiment
Pink sandstone	Pink sandstone	Pink sandstone
Pyrite	Pyrite	Pyrite
Pyrolusite	Pyrolusite	Pyrolusite
Quartz conglomerate	Quartz conglomerate	Quartz conglomerate
Rhodonite	Rhodonite	Rhodonite
Saccharoid marble	Saccharoid marble	Saccharoid marble
Sphalerite	Sphalerite; Blende; Zinc Blende	Sphalerite
Scapolite	Scapolite; Feldspar	Scapolite
Sea sand	Sea sand; Silica marina	Sea sand
Silver	Silver	Silver
Sulphur	Sulphur	Sulphur

Proper name(s)	Common name(s)	Source material(s)
Stibnite	Stibnite	Stibnite
Trachyte	Trachyte	Trachyte
Ulexite	Ulexite	Ulexite
Uraninite	Uraninite	Uraninite

Route(s) of administration

- ▶ Oral
- ▶ Rectal (for Pink sandstone only)

Dosage form(s)

The acceptable pharmaceutical dosage forms must be one listed in Table 2 below.

Use(s) or Purpose(s) Statement(s) to the effect of

Lithotherapy preparation/remedy/medicine

Dose Statement(s) to the effect of

Subpopulation(s)

Adults (≥ 18 years)

Quantity(ies)

The dilution for each medicinal ingredient must be equal to or greater than D8 (or equivalent).

Table 2 Dosage information guidelines

Dosage form	Maximum Amount per dose	Maximum Frequency	Maximum Acute Dosing (Optional)
Globules (small pellets, pilules)	1 whole unit dose (tube of container)	Once per day	1 unit dose, 3 times per day



Dosage form	Maximum Amount per dose	Maximum Frequency	Maximum Acute Dosing (Optional)
Granules (regular and large pellets)	5 granules	3 times per day	Every 15-60 minutes (up to 12 times per day) or until improvement of symptoms. Then resume general dosing.
Tablets	4 tablets	4 times per day	Every 15-60 minutes (up to 12 times per day) or until improvement of symptoms. Then resume general dosing.
Oral Drops	30 drops	3 times per day	Every 15-60 minutes (up to 12 times per day) or until improvement of symptoms. Then resume general dosing.
Liquids (Oral drinkable vials)	1 ampoule	3 times per day	Up to three times per day.
Oral solutions (Unit dose)	Unit oral dose	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.
Mouth sprays	1 spray	5 times per day	Every 30-60 minutes (up to 12 times per day) or until improvement of symptoms. The resume general dosing.
Suppositories	1 suppository	4 times per day	Maximum 5 times per day.

Method of preparation

The method of preparation must be:

Ph. Eur. monograph 1038.

Directions for use

Take as directed by a health care practitioner.

Duration of use

No statement required.

Risk information

Cautions and warnings

All products

- ▶ If symptoms persist or worsen, consult a health care practitioner.
- ▶ If you are pregnant or breastfeeding, consult a health care practitioner prior to use.

Products administered rectally

If insertion of the suppository into the rectum causes pain or bleeding, discontinue use and consult a health care practitioner promptly.

Contraindications

No statement required.

Known adverse reactions

No statement required.

Non-medicinal ingredients

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

Specifications

- ▶ The finished product specifications must be established in accordance with the requirements described in the NHPD *Quality of Natural Health Products Guide*.
- ▶ The medicinal ingredient must comply with the requirements outlined in the *Natural Health Products Ingredients Database* (NHPID).

References reviewed

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IMA-CNMNC 2006: The Commission on New Minerals, Nomenclature and Classification (CNMNC) of the International Mineralogical Association (IMA) Sydney (Australia) [Internet] [Accessed 2013 May 29]. Available from: <http://pubsites.uws.edu.au/ima-cnmnc/>

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