Lithotherapy

Lithotherapy 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 - 115 K) This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA s) 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 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 on the label. The use of the web-based PLA is not possible where reference is made to this monograph. Please use the PDF format available at: https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/prodnatur/applications/licen-prod/form/form_pl-dlmm-eng.pdf . This monograph cannot be combined with any other monograph at Class II. Date January 10, 2025 Proper name(s), Common name(s), Source information 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 Dolomite Dolomite Dolomite Erythrite Erythrite Erythrite Fluorite Fluorite Fluorite Galena Galena Galena Garnierite Garnierite Garnierite Glauconite Glauconite Glauconite 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 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) This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document. The acceptable dosage forms must be one listed in Table 2 below. Use(s) or Purpose(s) Lithotherapy preparation/remedy/medicine. Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) The dilution for each medicinal ingredient must be equal to or greater than D8 (or equivalent). Table 2. Dosage information Dosage forms Maximum General Dosing Maximum Acute Dosing Amount Frequency (Optional) Globules (small pellets, pilules) 1 whole unit dose (tube of container) 1 time per day 1 unit dose, 3 times per day Globules (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. Oral spray 10-15 sprays 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 3 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. Suppositories 1 suppository 4 times per day Up to 5 times per day Method(s) of preparation The method of preparation must be: Ph. Eur. 1 monograph 1038. 1 Note: European Pharmacopoeia Direction(s) for use Use/Take 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) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Ask a health

care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Products administered rectally Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if insertion of the suppository into the rectum causes pain or bleeding. 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 Must be established in accordance with the requirements described in the Natural Health Products Regulations . Specifications 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 must comply with the requirements outlined in the NHPID. EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details. References cited Ph.Eur. 2024: European Pharmacopoeia, 11th edition. Strasbourg (FR): Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM), 2024. The most current version applies. References reviewed Bergeret C, Tétau M. Précis de lithothérapie déchélatrice. (FR) : Éditions Maloine, 1984. Binet C. Oligo-éléments et oligothérapie. (FR) : Dangles, 2007. Brigo B. Logique thérapeutique des oligoéléments et des remèdes en lithothérapie. (BE) : Marco Pietteur éditeur, 2005. IMA 2023: International Mineralogical Association. [Accessed 2024 August 8]. Available from: https://mineralogy-ima-wordpress.website/ IMA-CNMNC 2023: The Commission on New Minerals, Nomenclature and Classification (CNMNC) of the International Mineralogical Association (IMA) [Accessed 2023 August 8]. Available from: http://cnmnc.units.it/ MinSoc 2024: Mineralogical Society of Great Britain and Ireland. Middlesex (GB). [Accessed 2024 August 8]. Available from: http://www.minersoc.org/ Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

Notes By submitting aPLAreferencing 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 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 on the label.The use of the web-based PLA is not possible where reference is made to this monograph. Please use the PDF format available at:https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/prodnatur/applications/licen-prod/form/form_pl-dlmm-eng.pdf.This monograph cannot be combined with any other monograph at Class II. Date January 10, 2025 Proper name(s), Common name(s), Source information Table 1.Products may contain one or more of the following ingredientsProper name(s)Common name(s)Source material(s)AdulariaAdulariaAdulariaApatiteApatiteApatiteAzuriteAzuriteAzuriteBaryteBaryte; BarytineBaryteBauxiteBauxiteBauxiteBetafiteBetafiteBetafiteBorniteBorniteBorniteCalciteCalciteCalciteCelestineCelestine; CelestiteCelestineCinnabarCinnabarCinnabarDiopsideDiopsideDiopsideDolomiteDolomiteDolomiteErythriteErythriteErythriteFluoriteFluoriteFluoriteGalenaGalenaGalenaGarnieriteGarnieriteGarnieriteGlauconiteGlauconiteGlauconiteGraniteGraniteGraniteGraphiteGraphiteGraphiteGreen jasperGreen jasperGreen jasperHaliteHaliteHaliteHematiteHematiteHematiteIodargyriteIodargyriteIodargyriteLazuliteLazuliteLazuliteLepidoliteLepidoliteLepidoliteMonaziteMonaziteMonaziteObsidianObsidianObsidianOrpimentOrpimentOrpimentPink sandstonePink sandstonePink sandstonePyritePyritePyritePyrolusitePyrolusitePyrolusiteQuartz conglomerateQuartz conglomerateQuartz conglomerateRhodoniteRhodoniteRhodoniteSaccharoid marbleSaccharoid marbleSaccharoid marbleSphaleriteSphalerite; Blende; Zinc BlendeSphaleriteScapoliteScapolite; FeldsparScapoliteSea sandSea sand; Silica marinaSea sandSilverSilverSilverSulphurSulphurSulphurStibniteStibniteStibniteTrachyteTrachyteTrachyteUlexiteUlexiteUlexiteUraniniteUraniniteUraninite

DOSAGE FORM(S)

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

DOSE(S)

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 the statements are synonymous. Either term or statement may be selected by the applicant on the label. The use of the web-based PLA is not possible where reference is made to this monograph. Please use the PDF format available at:https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/prodnatur/applications/licen-prod/form/form_pl-dlmm-eng.pdf. This monograph cannot be combined with any other monograph at Class II.

RISK INFORMATION

Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding.Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Products administered rectally Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if insertion of the suppository into the rectum causes pain or bleeding. 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 Must be established in accordance with the requirements described in theNatural Health Products Regulations.

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in theNatural Health Products Regulations.

SPECIFICATIONS

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 must comply with the requirements outlined in the NHPID. EXAMPLE OF PRODUCT FACTS:Consult the Guidance Document,Labelling of Natural Health Productsfor more details.

REFERENCES

Ph.Eur. 2024: European Pharmacopoeia, 11th edition. Strasbourg (FR): Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM), 2024. The most current version applies. References reviewed Bergeret C, Tétau M. Précis de lithothérapie déchélatrice. (FR) : Éditions Maloine, 1984.Binet C.

Oligo-éléments et oligothérapie. (FR) : Dangles, 2007.Brigo B. Logique thérapeutique des oligoéléments et des remèdes en lithothérapie. (BE) : Marco Pietteur éditeur, 2005.IMA 2023: International Mineralogical Association. [Accessed 2024 August 8]. Available from: https://mineralogy-ima-wordpress.website/IMA-CNMNC 2023: The Commission on New Minerals, Nomenclature and Classification (CNMNC) of the International Mineralogical Association (IMA) [Accessed 2023 August 8]. Available from: http://cnmnc.units.it/MinSoc 2024: Mineralogical Society of Great Britain and Ireland. Middlesex (GB). [Accessed 2024 August 8]. Available from: http://www.minersoc.org/

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
Dolomite	Dolomite	Dolomite
Erythrite	Erythrite	Erythrite
Fluorite	Fluorite	Fluorite
Galena	Galena	Galena
Garnierite	Garnierite	Garnierite
Glauconite	Glauconite	Glauconite
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
Stibnite	Stibnite	Stibnite
Trachyte	Trachyte	Trachyte
Ulexite	Ulexite	Ulexite
Uraninite	Uraninite	Uraninite

e forms	Maximum General Dosing	Maximum Acute Dosing	
t	Frequency	(Optional)	
s (small pellets, pilules)	1 whole unit dose (tube of container)	1 time per day	1 unit dose, 3 times per day
s (regular and large pellets)	5 granules	3 times per day	Every 15-60 minutes (up to 12 time
	4 tablets	4 times per day	Every 15-60 minutes (up to 12 time
ops	30 drops	3 times per day	Every 15-60 minutes (up to 12 time
ray	10-15 sprays	3 times per day	Every 15-60 minutes (up to 12 time
(Oral drinkable vials)	1 ampoule	3 times per day	Up to 3 times per day
lutions (Unit dose)	Unit oral dose	3 times per day	Give one unit dose upon onset of s
itories	1 suppository	4 times per day	Up to 5 times per day