

Organotherapy

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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) Table 1. Proper name(s), Common name(s) Proper name(s) Common name(s) Anas barbariae Duck Cavia porcellus Guinea pig Danio rerio Zebra danio/Zebrafish Gallus gallus domesticus Chicken Sus scrofa Pig Oryctolagus cuniculus Rabbit Source information Please refer to Appendix I. Route(s) of administration Oral Sublingual Nasal Ophthalmic Topical Rectal 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 are those indicated in Table 2 below. Use(s) or Purpose(s) Organotherapy (preparation/remedy/medicine). Dose(s) Subpopulation(s) Adolescent 13-17 years, Adults 18 and older Quantity(ies) The dilution for each medicinal ingredient must be equal to or greater than 3X (or equivalent). Table 2. Dosing information Dosage form(s) 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 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. 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) 1 unit 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. Oral Syrups 1-2 teaspoons Every 4-6 hours Not applicable Creams/Ointments Cover affected area As needed Not applicable Nasal Sprays 2 sprays/nostril 5 times per day Not applicable Suppositories 1 suppository 1-4 times per day Up to 4 times per day Method(s) of preparation The method of preparation must be one of the following: HPUS 1 Class L, Method I or II; HAB 2 method 42 a or b; PhF 3 mother tinctures for drugs of animal origins; or Ph. Eur. 4 monograph 1038 Notes: 1 Homeopathic Pharmacopoeia of the United States 2 Homöopathisches ArzneiBuch. 3 French Pharmacopoeia 4 European Pharmacopoeia Direction(s) of 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) Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Contraindication(s) Do not use if you are pregnant or breastfeeding. Known adverse reaction(s) No statement required. Non-Medicinal Ingredient(s) 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. 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.

EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details. References cited HAB 2023: Homöopathisches ArzneiBuch. Deutscher Apotheker Verlag, 2024. The most current version applies. HPUS 2024: Homeopathic Pharmacopeia of the United States, Online: Homeopathic Pharmacopoeia Convention of the United States, 2024. The most current version applies. 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. PhF 2024: French Pharmacopoeia, 11th edition. Saint-Denis Cedex (FR) : French Agency for the Safety of Health Products, 2024. The most current version applies. References reviewed Reckeweg HH. Organ Therapy. Homotoxin-Journal. Journal for Holistic Research and Synthesis in Medicine 1963;6(1):317-320. Rozenecwajg J. Organotherapy, Drainage and Detoxification. Kandern (Germany): Natura Medical Ltd, 2010. Tétau M, Bergeret C. L'organothérapie diluée et dynamisée. Paris (FR) : éditions Maloine, 1973. Tétau M. Nouvelles cliniques d'organothérapie diluée et dynamisée. Paris (FR): éditions Similia, 1986. Appendix I Acceptable Source Materials for Organotherapy Medicinal Ingredients. A B C D E F G H I J K L M N O P Q R S T U V W Y A Adipose tissue Adrenal cortex/Suprarenal cortex Adrenal gland/Suprarenal gland Adrenal medulla Adrenal gland/Suprarenal gland Ankle articulation Anterior cruciate ligament Anterior pituitary gland/Andenohypophysis Aorta Appendix/Caecum Aqueous humor Artery Articular capsule Ascending colon Atlas Auditory nerve Auricle Auriculo-ventricular wall B Bile Bladder Blood Blood plasma Bone marrow Bones Brachial plexus Brain/Encephalon/Whole brain Bronchial mucosa Bronchus C Calcaneal tendon/Achilles tendon Canal of cervix Capillary tissue Cardia/Esophagogastric junction Carotid artery Carotid plexus Cartilage Cephalorachidien liquid Cerebellum Cerebral artery Cerebral cortex Cerebral cortex and hypothalamus Cervical disc Cervical marrow Cervical vertebrae Choroid Ciliary body Coccyx Collagen Colon Common bile duct Conjunctiva Conjunctive tissue Cornea Coronary artery Coronary vein Corpus callosum Corpus cavernosum Corpus luteum/Yellow body Corpus spongiosum Cortex and hypothalamus Coxo-femoral cartilage Cranial nerve Crystallin Cubital nerve/Ulnar nerve Cystic duct D Deferent duct/Vas deferens Dental pulp Descending colon Diaphragm Diencephalon/Interbrain Dorsal marrow Dorsal vertebrae Duodenum E Elbow articulation Elbow ligament Embryo Endocardium Endothelium tissue (Bone marrow + spleen + thymus) Epididymis Epiphysis/Pineal body/Pineal gland Epiphyseal cartilage Eye Eustachian tube F Facial nerve Fallopian tube Femoral artery Fibrin First cervical vertebrae Flat bone Frontal lobe G Gall bladder Gizzard Glossopharyngeal nerve Gray matter Greater curvature of the stomach Gums H Hair Heart Heart ventricles Hemorrhoidal vein/Rectal vein/Anal vein Hepatic duct Hepatopancreatic sphincter Hip articulation Hip ligament Hippocampus Hyaline cartilage Hypogastric plexus Hypothalamus I Ileocecal valve Ileum Inferior vena cava Internal ear Intervertebral discs Intestinal mucosa J Jejunum K Kidney Knee articulation Knee ligament L Labyrinth Lacrimal glands Larynx Left ventricle Lens of the eye Ligaments Limbic system Liver Long bone Lower portion of the brain stem Lumbar discs Lumbar marrow Lumbar plexus Lumbar vertebrae Lung Lung with histamine Lymph gland/Lymphatic gland Lymph vessel/Lymphatic vessels Lymphatic ganglia Lymphatic node M Mammary glands Medial collateral ligament Median nerve Medulla oblongata Meninges Meniscus Mesencephalon Middle ear Minor curvature of the stomach Mitral valve Mucosa of the bile duct Mucosa of the bladder Mucosa of the colon Mucosa of the duodenum Mucosa of the duodenum and pylorus Mucosa of the gall bladder Mucosa of the gums Mucosa of the ileum Mucosa of the intestine Mucosa of the jejunum Mucosa of the lung Mucosa of the oesophagus Mucosa of the pyloric region Mucosa of the rectum Mucosa of the rectum and sigmoid Mucosa of the rhinopharynx Mucosa of the sinus Mucosa of the small intestine Mucosa of the stomach Myocardia Muscles N Nail Nasal mucosa Natural/Genuine lard Neck of urinary bladder Nerve Nervous tissue O Occipital lobe Occipital nerve Ocular muscle Oculomotor nerve Oesophagus Olfactive nerve Olfactory bulb Ophthalmic artery Optic chiasma Optic nerve Optic thalamus Oral mucosa Orbicular muscle of eye Ossicles Ovary P Pancreas Pancreatic duct Parathyroid Parietal lobe Parotid gland Pelvis of the kidney Penis Pericardium Periodontium Peritoneum Periosteum Peyer's patches Pharyngeal tonsil/Adenoids Pharynx Pilosebaceous glands (cranial region) Pituitary gland/Hypophysis Placenta Pleura Pons Posterior cruciate ligament Posterior pituitary gland/Neurohypophysis Poultry gizzard Prostate Pulmonary artery Q Quadrigeminal bodies R Radial nerve Rectum Red blood cells Red bone marrow Renal cortex Renal medulla Reticuloendothelial system Retina Right ventricle Rhinencephalon S Sacral marrow Sacral plexus Sacral vertebrae Salivary glands Saphenous vein Sciatic nerve Second cervical vertebrae Seminal vesicle Short bone Shoulder articulation Shoulder ligament Sigmoid colon Small bronchi mucosa Small intestine Smooth muscle Solar plexus Spinal cord Spleen Spongy bone Stomach Striated muscle Submandibular gland Sympathetic ganglia Sympathetic nerve Synovial fluid T Tegument/Skin Temporal lobe Temporomandibular articulation Tendon Testis Thalamus Thoracic discs Thoracic vertebrae Thymus gland Thyroid gland Tongue Tonsil Tooth Trachea Transverse colon Trigeminal nerve Tympanic membrane U Umbilical cord Ureter Urethral sphincter Uterovesical junction Urethra Uterus V Vaginal mucosa Vagus nerve Vegetative ganglia Vein Vertebrae Vertebral column ligament

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.

DOSAGE FORM(S)

The acceptable dosage forms are those indicated 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 f This monograph cannot be combined with any other monograph at Class II.

RISK INFORMATION

Caution(s) and warning(s) Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Contraindication(s) Do not use if you are pregnant or breastfeeding. Known adverse reaction(s) No statement required.

STORAGE CONDITION(S)

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. 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.

REFERENCES

HAB 2023: Homöopathisches ArzneiBuch. Deutscher Apotheker Verlag, 2024. The most current version applies. HPUS 2024: Homeopathic Pharmacopeia of the United States, Online: Homeopathic Pharmacopoeia Convention of the United States, 2024. The most current version applies. 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. PhF 2024: French Pharmacopoeia, 11th edition. Saint-Denis Cedex (FR) : French Agency for the Safety of Health Products, 2024. The most current version applies. References reviewed

Reckeweg HH. Organ Therapy. Homotoxin-Journal. Journal for Holistic Research and Synthesis in Medicine 1963;6(1):317-320.

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Tétau M, Bergeret C. L'organothérapie diluée et dynamisée. Paris (FR) : éditions Maloine, 1973.

Tétau M. Nouvelles cliniques d'organothérapie diluée et dynamisée. Paris (FR): éditions Similia, 1986.

Appendix I Acceptable Source Materials for Organotherapy Medicinal Ingredients.

ABCDEFGHIJKLMNOPQRSTUVWXYZAdipose tissueAdrenal cortex/Suprarenal cortexAdrenal gland/Suprarenal glandAdrenal medullaAdrenal gland/Suprarenal glandAnkle articulationAnterior cruciate ligamentAnterior pituitary gland/AndenohypophysisAortaAppendix/CaecumAqueous humorArteryArticular capsuleAscending colonAtlasAuditory nerveAuricleAuriculo-ventricular wallBBileBladderBloodBlood plasmaBone marrowBonesBrachial plexusBrain/Encephalon/Whole brainBronchial mucosaBronchusCCalcaneal tendon/Achilles tendonCanal of cervixCapillary tissueCardia/Esophagogastric junctionCarotid arteryCarotid plexusCartilageCephalorachidien liquidCerebellumCerebral arteryCerebral cortexCerebral cortex and hypothalamusCervical discCervical marrowCervical vertebraeChoroidCiliary bodyCoccyxCollagenColonCommon bile ductConjunctivaConjunctive tissueCorneaCoronary arteryCoronary veinCorpus callosumCorpus cavernosumCorpus luteum/Yellow bodyCorpus spongiosumCortex and hypothalamusCoxo-femoral cartilageCranial nerveCrystallinCubital nerve/Ulnar nerveCystic ductDDeferent duct/Vas deferensDental pulpDescending colonDiaphragmDiencephalon/InterbrainDorsal marrowDorsal vertebraeDuodenumEElbow articulationElbow ligamentEmbryoEndocardiumEndothelium tissue (Bone marrow + spleen + thymus)EpididymisEpiphysis/Pineal body/Pineal glandEpiphyseal cartilageEyeEustachian tubeFFacial nerveFallopian tubeFemoral arteryFibrinFirst cervical vertebraeFlat boneFrontal lobeGGall bladderGizzardGlossopharyngeal nerveGray matterGreater curvature of the stomachGumsHHairHeartHeart ventriclesHemorrhoidal vein/Rectal vein/Anal veinHepatic ductHepatopancreatic sphincterHip articulationHip ligamentHippocampusHyaline cartilageHypogastric plexusHypothalamusIIleocecal valvulleumInferior vena cavalInternal earIntervertebral discsIntestinal mucosaJJejunumKKidneyKnee articulationKnee ligamentLLabyrinthLacrimal glandsLarynxLeft ventricleLens of the eyeLigamentsLimbic systemLiverLong boneLower portion of the brain stemLumbar discsLumbar marrowLumbar plexusLumbar vertebraeLungLung with histamineLymph gland/Lymphatic glandLymph vessel/Lymphatic vesselsLymphatic ganglia Lymphatic nodeMMammary glandsMedial collateral ligamentMedian nerveMedulla oblongataMeningesMeniscusMesencephalonMiddle earMinor curvature of the stomachMitral valveMucosa of the bile ductMucosa of the bladderMucosa of the colonMucosa of the duodenumMucosa of the duodenum and pylorusMucosa of the gall bladderMucosa of the gumsMucosa of the ileumMucosa of the intestineMucosa of the jejunumMucosa of the lungMucosa of the oesophagusMucosa of the pyloric regionMucosa of the rectumMucosa of the rectum and sigmoidMucosa of the rhinopharynxMucosa of the sinusMucosa of the small intestineMucosa of the stomachMyocardiaMusclesNNailNasal mucosaNatural/Genuine lardNeck of urinary bladderNerveNervous tissueOOccipital lobeOccipital nerveOcular muscleOculomotor nerveOesophagusOlfactive nerveOlfactory bulbOphthalmic arteryOptic chiasmaOptic nerveOptic thalamusOral mucosaOrbicular muscle of eyeOssiclesOvaryPPancreasPancreatic ductParathyroidParietal lobeParotid glandPelvis of the kidneyPenisPericardiumPeriodontiumPeritoneumPeriosteumPeyer's patchesPharyngeal tonsil/AdenoidsPharynxPilosebaceous glands (cranial region)Pituitary

gland/HypophysisPlacentaPleuraPonsPosterior cruciate ligamentPosterior pituitary
gland/NeurohypophysisPoultry gizzardProstatePulmonary arteryQQuadrigeminal bodiesRRadial
nerveRectumRed blood cellsRed bone marrowRenal cortexRenal medullaReticuloendothelial
systemRetinaRight ventricleRhencephalonSSacral marrowSacral plexusSacral vertebraeSalivary
glandsSaphenous veinSciatic nerveSecond cervical vertebraeSeminal vesicleShort boneShoulder
articulationShoulder ligamentSigmoid colonSmall bronchi mucosaSmall intestineSmooth muscleSolar
plexusSpinal cordSpleenSpongy boneStomachStriated muscleSubmandibular glandSympathetic
gangliaSympathetic nerveSynovial fluidTTegument/SkinTemporal lobeTemporomandibular
articulationTendonTestisThalamusThoracic discsThoracic vertebraeThymus glandThyroid
glandTongueTonsilToothTracheaTransverse colonTrigeminal nerveTympanic membraneUmbilical
cordUreterUrethral sphincterUreterovesical junctionUrethraUterusVVaginal mucosaVagus nerveVegetative
gangliaVeinVertebraeVertebral column ligamentVertebral ligamentVesical trigoneVitreous humourVulvaWWhite
matterYYellow bone marrow

Proper name(s)	Common name(s)
Anas barbariae	Duck
Cavia porcellus	Guinea pig
Danio rerio	Zebra danio/Zebrafish
Gallus gallus domesticus	Chicken
Sus scrofa	Pig
Oryctolagus cuniculus	Rabbit

Form(s)	Maximum General Dosing	Maximum Acute Dosing	
t	Frequency	(Optional)	
es (small pellets, pilules)	1 whole unit dose (tube of container)	1 time per day	1 unit dose, 3 times per day
es (regular and large pellets)	5 granules	3 times per day	Every 15-60 minutes (up to 12 times per day) of symptoms. Then resume s
	4 tablets	4 times per day	Every 15-60 minutes (up to 12 times per day) of symptoms. Then resume s
ops	30 drops	3 times per day	Every 15-60 minutes (up to 12 times per day) of symptoms. Then resume s
ray	10-15 sprays	3 times per day	Every 15-60 minutes (up to 12 times per day)
(oral drinkable vials)	1 ampoule	3 times per day	Up to 3 times per day
olutions (unit dose)	1 unit dose	3 times per day	Give one unit dose upon onset of s at 15-minute intervals. Repeat if symptoms reappear.
rops	1-2 teaspoons	Every 4-6 hours	Not applicable
s/Ointments	Cover affected area	As needed	Not applicable
psays	2 sprays/nostril	5 times per day	Not applicable
itories	1 suppository	1-4 times per day	Up to 4 times per day