



NATURAL HEALTH PRODUCT

ORGANOTHERAPY

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.
- ▶ 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) and Common name(s)

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

Source material(s)

Please refer to Appendix I.

Route(s) of administration

- ▶ Oral

- ▶ Sublingual
- ▶ Nasal
- ▶ Ophthalmic
- ▶ Topical
- ▶ Rectal

Dosage form(s)

- ▶ The acceptable pharmaceutical dosage forms include, but are not limited to those indicated in Table 1 below,
- ▶ The acceptable pharmaceutical dosage forms should be suited to the route(s) of administration.
- ▶ 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

Organotherapy preparation/remedy/medicine

Dose(s)

Subpopulation

Adults (≥18 years) and adolescents (13-17 years)

Quantity(ies)

The dilution for each medicinal ingredient must be equal to or greater than 3X (or equivalent).

Table 1 Dosing information guidelines

| Dosage form(s) | Maximum General Dosing | Maximum Frequency | Maximum Acute Dosing (Optional) |
|--------------------------------------|---------------------------------------|-------------------|---|
| Globules (small pellets, pilules) | 1 whole unit dose (tube of container) | Once per day | 20 globules, 3 times daily |
| 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 |

| Dosage form(s) | Maximum General Dosing | Maximum Frequency | Maximum Acute Dosing (Optional) |
|--------------------------------|------------------------|-------------------|---|
| 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) | 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 tsp | 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 | Maximum 4 times per day |

Method of preparation

The method of preparation must be one of the following:

- ▶ HPUS Class L, Method I or II;
- ▶ HAB method 42 a or b;
- ▶ PhF mother tinctures for drugs of animal origins; or
- ▶ Ph. Eur. monograph 1038

Directions for use

Take as directed by a health care practitioner.

Duration of use

No statement required.

Risk information Statement to the effect of

Cautions and warnings

If symptoms persist or worsen, consult a health care practitioner.

Contraindications

If you are pregnant or breastfeeding, do not use this product.

Known adverse reactions

No statement required.

Non-Medicinal Ingredient(s)

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).
- ▶ 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 reviewed

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

Rozencwajg 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.

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|--|------------------------------------|
| Adipose tissue | Appendix/Caecum |
| Adrenal cortex/Suprarenal cortex | Aqueous humor |
| Adrenal gland/Suprarenal gland | Artery |
| Adrenal medulla | Articular capsule |
| Adrenal gland/Suprarenal gland | Ascending colon |
| Ankle articulation | Atlas |
| Anterior cruciate ligament | Auditory nerve |
| Anterior pituitary gland/Andenohypophysis | Auricle |
| Aorta | Auriculo-ventricular wall |
| Bile | Bones |
| Bladder | Brachial plexus |
| Blood | Brain/Encephalon/Whole brain |
| Blood plasma | Bronchial mucosa |
| Bone marrow | Bronchus |
| Calcaneal tendon/Achilles tendon | Collagen |
| Canal of cervix | Colon |
| Capillary tissue | Common bile duct |
| Cardia/Esophagogastric junction | Conjunctiva |
| Carotid artery | Conjunctive tissue |
| Carotid plexus | Cornea |
| Cartilage | Coronary artery |
| Cephalorachidien liquid | Coronary vein |
| Cerebellum | Corpus callosum |
| Cerebral artery | Corpus cavernosum |
| Cerebral cortex | Corpus luteum/Yellow body |
| Cerebral cortex and hypothalamus | Corpus spongiosum |
| Cervical disc | Cortex and hypothalamus |
| Cervical marrow | Coxo-femoral cartilage |
| Cervical vertebrae | Cranial nerve |
| Choroid | Crystallin |
| Ciliary body | Cubital nerve/Ulnar nerve |
| Coccyx | Cystic duct |
| Deferent duct/Vas deferens | Diencephalon/Interbrain |
| Dental pulp | Dorsal marrow |
| Descending colon | Dorsal vertebrae |
| Diaphragm | Duodenum |
| Elbow articulation | Epididymis |
| Elbow ligament | Epiphysis/Pineal body/Pineal gland |
| Embryo | Epiphyseal cartilage |
| Endocardium | Eye |
| Endothelium tissue (Bone marrow + spleen + thymus) | Eustachian tube |



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|---|----------------------------------|
| Facial nerve | First cervical vertebrae |
| Fallopian tube | Flat bone |
| Femoral artery | Frontal lobe |
| Fibrin | |
| Gall bladder | Gray matter |
| Gizzard | Greater curvature of the stomach |
| Glossopharyngeal nerve | Gums |
| Hair | Hip articulation |
| Heart | Hip ligament |
| Heart ventricles | Hippocampus |
| Hemorrhoidal vein/Rectal vein/Anal vein | Hyaline cartilage |
| Hepatic duct | Hypogastric plexus |
| Hepatopancreatic sphincter | Hypothalamus |
| Ileocecal valve | Internal ear |
| Ileum | Intervertebral discs |
| Inferior vena cava | Intestinal mucosa |
| Jejunum | |
| Kidney | Knee ligament |
| Knee articulation | |
| Labyrinth | Lumbar discs |
| Lacrimal glands | Lumbar marrow |
| Larynx | Lumbar plexus |
| Left ventricle | Lumbar vertebrae |
| Lens of the eye | Lung |
| Ligaments | Lung with histamine |
| Limbic system | Lymph gland/Lymphatic gland |
| Liver | Lymph vessel/Lymphatic vessels |
| Long bone | Lymphatic ganglia |
| Lower portion of the brain stem | Lymphatic node |



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|------------------------------------|---|
| Mammary glands | Mucosa of the gums |
| Medial collateral ligament | Mucosa of the ileum |
| Median nerve | Mucosa of the intestine |
| Medulla oblongata | Mucosa of the jejunum |
| Meninges | Mucosa of the lung |
| Meniscus | Mucosa of the oesophagus |
| Mesencephalon | Mucosa of the pyloric region |
| Middle ear | Mucosa of the rectum |
| Minor curvature of the stomach | Mucosa of the rectum and sigmoid |
| Mitral valve | Mucosa of the rhinopharynx |
| Mucosa of the bile duct | Mucosa of the sinus |
| Mucosa of the bladder | Mucosa of the small intestine |
| Mucosa of the colon | Mucosa of the stomach |
| Mucosa of the duodenum | Myocardia |
| Mucosa of the duodenum and pylorus | Muscles |
| Mucosa of the gall bladder | |
| Nail | Neck of urinary bladder |
| Nasal mucosa | Nerve |
| Natural/Genuine lard | Nervous tissue |
| Occipital lobe | Optic chiasma |
| Occipital nerve | Optic nerve |
| Ocular muscle | Optic thalamus |
| Oculomotor nerve | Oral mucosa |
| Oesophagus | Orbicular muscle of eye |
| Olfactive nerve | Ossicles |
| Olfactory bulb | Ovary |
| Ophthalmic artery | |
| Pancreas | Pharyngeal tonsil/Adenoids |
| Pancreatic duct | Pharynx |
| Parathyroid | Pilosebaceous glands (cranial region) |
| Parietal lobe | Pituitary gland/Hypophysis |
| Parotid gland | Placenta |
| Pelvis of the kidney | Pleura |
| Penis | Pons |
| Pericardium | Posterior cruciate ligament |
| Periodontium | Posterior pituitary gland/Neurohypophysis |
| Peritoneum | Poultry gizzard |
| Periosteum | Prostate |
| Peyer's patches | Pulmonary artery |
| Quadrigeminal bodies | |
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|--------------------------------|----------------------------|
| Radial nerve | Renal medulla |
| Rectum | Reticuloendothelial system |
| Red blood cells | Retina |
| Red bone marrow | Right ventricle |
| Renal cortex | Rhinencephalon |
| Sacral marrow | Small intestine |
| Sacral plexus | Smooth muscle |
| Sacral vertebrae | Solar plexus |
| Salivary glands | Spinal cord |
| Saphenous vein | Spleen |
| Sciatic nerve | Spongy bone |
| Second cervical vertebrae | Stomach |
| Seminal vesicle | Striated muscle |
| Short bone | Submandibular gland |
| Shoulder articulation | Sympathetic ganglia |
| Shoulder ligament | Sympathetic nerve |
| Sigmoid colon | Synovial fluid |
| Small bronchi mucosa | |
| Tegument/Skin | Thyroid gland |
| Temporal lobe | Tongue |
| Temporomandibular articulation | Tonsil |
| Tendon | Tooth |
| Testis | Trachea |
| Thalamus | Transverse colon |
| Thoracic discs | Trigeminal nerve |
| Thoracic vertebrae | Tympanic membrane |
| Thymus gland | |
| Umbilical cord | Ureterovesical junction |
| Ureter | Urethra |
| Urethral sphincter | Uterus |
| Vaginal mucosa | Vertebral column ligament |
| Vagus nerve | Vertebral ligament |
| Vegetative ganglia | Vesical trigone |
| Vein | Vitreous humour |
| Vertabrae | Vulva |
| White matter | |
| Yellow bone marrow | |