



## NATURAL HEALTH PRODUCT

### OLIGOTHERAPY

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)**

Please refer to Table 1 and 2 below.

#### **Route(s) of administration**

- ▶ Oral
- ▶ Sublingual

#### **Dosage form(s)**

- ▶ The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.
- ▶ This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.
- ▶ The acceptable pharmaceutical dosage forms suited to sublingual administration.

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



Oligotherapy preparation/remedy/medicine

**Dose(s)** Statement(s) to the effect of

**Subpopulation(s)**

Adults ( $\geq 18$  years)

**Quantity(ies)**

*All products except those specified below*

1 dosage unit, 1-2 times per day.

**Dosage information for specific single ingredient products:**

*Products containing only Bismuth as a medicinal ingredient*

1 dosage unit every 3 hours up to 8 times per day for 3-5 days.

*Products containing Cobalt as a medicinal ingredient*

1 dosage unit per day.

*Products containing only Copper as a medicinal ingredient*

1 dosage unit every 3 hours up to 8 times per day for 3-5 days.

*Products containing only Iodine, Iron, Magnesium, Phosphorus or Zinc as a medicinal ingredient*

1 dosage unit, 1-2 times per day

**Dosage information for specific multi-ingredient products:**

*Products containing only Zinc and Copper in combination as medicinal ingredient*

1 dosage unit, 1-2 times per day

*Products containing Copper, Gold and Silver in combination as medicinal ingredients*

1 dosage unit, 1-2 times per day.

**Table 1** Proper name(s), Common name(s), Source material(s) and Dosage information for single ingredient preparation



<b>Proper name(s)</b>	<b>Common name(s)</b>	<b>Source material(s)</b>	<b>Maximum quantity per dosage unit (µg)</b>
Aluminium	Aluminium	Aluminium gluconate	176
Bismuth	Bismuth	Bismuth gluconate	70
Cobalt	Cobalt	Cobalt gluconate	59
Chromium	Chromium	Chromium (III) chloride	25
Copper	Copper	Copper gluconate	725.2
Fluoride	Fluoride	Sodium fluoride	200
Iodine	Iodine	Sodium iodide; Potassium iodide	24
Iron	Iron	Iron gluconate	14
Magnesium	Magnesium	Magnesium gluconate	104.4
Manganese	Manganese	Manganese gluconate	72.8
Nickel	Nickel	Nickel gluconate	72.6
Phosphorus	Phosphorus	Disodium phosphate	140
Potassium	Potassium	Potassium gluconate	40



Proper name(s)	Common name(s)	Source material(s)	Maximum quantity per dosage unit (µg)
Selenium	Selenium	Selenite sodium	100
Sulphur	Sulphur	Sodium thiosulfate	122
Zinc	Zinc	Zinc gluconate	67.4

**Table 2** Proper name(s), Common name(s), Source material(s) and Dosage information for multi-ingredient preparation containing one of the following combination

Proper name(s)	Common name(s)	Source material(s)	Quantity per dosage unit (µg)
Manganese; Cobalt	Manganese; Cobalt	Manganese gluconate; Cobalt gluconate	72.8; 72.6
Manganese; Copper; Cobalt	Manganese; Copper; Cobalt	Manganese gluconate; Copper gluconate; Cobalt gluconate	72.8; 72.6; 72.6
Manganese; Copper	Manganese; Copper	Manganese gluconate; Copper gluconate	72.8; 72.6
Cobalt; Nickel	Cobalt; Nickel	Cobalt gluconate Nickel gluconate;	72.6; 72.6
Copper; Zinc	Copper; Zinc;	Copper gluconate; Zinc gluconate	72.6; 67.4
Cobalt; Nickel; Zinc	Cobalt; Nickel; Zinc	Cobalt gluconate; Nickel gluconate; Zinc gluconate	72.6; 72.6; 67.4
Copper; Gold; Silver	Copper; Gold; Silver	Copper gluconate; Gold elemental; Silver gluconate	31; 98; 50
Copper; Gold; Silver	Copper; Gold; Silver	Copper gluconate; Gold elemental; Silver gluconate	63; 1.4; 21.36



Copper; Gold; Silver	Copper; Gold; Silver	Copper gluconate; Gold elemental; Silver gluconate	500; 0.2; 7.4
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**Directions for use**

*All product*

Take as directed by a health care practitioner.

*Products containing Iron or Zinc*

- ▶ Take a few hours before or after taking other medications (HC 2012; Martindale 2011).
- ▶ Take with food (HC 2012; Martindale 2011).

**Duration of use** Statement(s) to the effect of

Use for up to two months or as recommended by a health care practitioner (Brigo 1999).

**Risk information** Statement(s) to the effect of

**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 containing Aluminium*

If you have renal impairment, consult a health care practitioner prior to use (JECFA 1988)

*Products containing Cobalt*

- ▶ If you are taking Vitamin B<sub>12</sub>, consult a health care practitioner prior to use (EVM 2003)
- ▶ If gastrointestinal upset and/or skin rashes occur, discontinue use and consult a health care practitioner.

*Products providing doses of Selenium ≥ 200 µg per day*

If you have a history of non-melanoma skin cancer, consult a health care practitioner prior to use.

**Contraindications**



### *Products containing Cobalt*

If you have an iodine deficiency, do not use this product (EVM 2003).

### *Products containing Manganese*

If you have tuberculosis or a history of tuberculosis, do not use this product (Padrazzi 1988; Ménétrier 1983).

### *Products containing Manganese and Cobalt*

If you have tuberculosis or a history of tuberculosis, do not use this product (Ménétrier 1983).

### *Products containing Zinc and/or Copper*

If you have cancer, tuberculosis or a history of tuberculosis, do not use this product (Padrazzi 1988; Ménétrier 1983).

## **Known adverse reactions**

### *Products containing Fluoride*

Using this product in an area where the drinking water has a natural fluorine content in excess of 0.7 parts of fluoride ion per million parts of water or is artificially fluoridated, may result in mottling of the tooth enamel.

## **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).

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