Oligotherapy

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Oligotherapy 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 - 132 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 form 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 Please refer to Tables 1 and 2 below. Route(s) of administration Oral Sublingual 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 capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets. Use(s) or Purpose(s) Oligotherapy preparation/remedy/medicine Dose(s) Subpopulation(s) Adults 18 years and older. 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. 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. 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 ingredients 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 information and Dosage information for single ingredient preparation Proper name(s) Common name(s) Source ingredient(s) Maximum quantity per dosage unit (µg) 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 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 information and Dosage information for multi-ingredient preparation containing one or more of the following ingredients Proper name(s) Common name(s) Source ingredient(s) Maximum 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 72.8 Manganese; Copper Manganese; Copper Manganese gluconate; Copper gluconate; 72.6 72.6 Cobalt; Nickel Cobalt; Nickel Cobalt gluconate Nickel gluconate; 72.6 72.6 Copper; Zinc Copper; Zinc Coppergluconate; 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 Direction(s) for use All products Use/Take as directed by a health care practitioner/health care provider/health care professional/doctor/physician. Products containing Iron or Zinc Take a few hours before or after taking other medications or health products (Health Canada 2023;

Sweetman 2017). Take with food (Health Canada 2023; Sweetman 2017). Duration(s) of use Products containing Bismuth and/or Copper Use for 3 - 5 days or as recommended by a health care practitioner/health care provider/health care professional/doctor/physician. Other products Use for up to 2 months or as recommended by a health care practitioner/health care provider/health care professional/doctor/physician (Brigo 1999). Risk information Cautions and warnings 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 containing Aluminium Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have a kidney disorder (JECFA 1987). Products containing Cobalt Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking Vitamin B12 (EVM 2003). Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if you experience gastrointestinal discomfort/disturbances and/or skin rashes. Products providing doses of Selenium ≥ 200 µg per day. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have a history of non-melanoma skin cancer. Contraindication(s) Products containing Cobalt Do not use if you have an iodine deficiency (EVM 2003). Products containing Manganese Do not use if you have tuberculosis or a history of tuberculosis (Padrazzi 1988; Ménétrier 1983). Products containing Manganese and Cobalt Do not use if you have tuberculosis or a history of tuberculosis (Ménétrier 1983). Products containing Zinc and/or Copper Do not use if you have cancer, tuberculosis or a history of tuberculosis (Padrazzi 1988; Ménétrier 1983). Known adverse reaction(s) Products containing Fluoride When using this product you may experience mottling of the tooth enamel 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. 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 Quality of Natural Health Products Guide. The finished product must comply with the minimum specifications outlined in the current NHPID . Example of Product Facts: Consult the Guidance Document, Labelling of Natural Health Products for more details. References cited Brigo, B. Logique thérapeutique des Oligoéléments et des remèdes en lithothérapie. Collection Résurgence. (LU): Marco Pietteur, editor, 1999. EVM 2003: Expert Group on Vitamins and Minerals. Safe Upper Levels for Vitamins and Minerals. May 2003. [Accessed 2024 August 29]. Available from: https://cot.food.gov.uk/sites/default/files/vitmin2003.pdf Health Canada 2023: Multi-vitamin/mineral supplements monograph. Natural and Non-prescription Health Products Directorate. Ottawa (ON). [Accessed 2024 August 26]. Available from: https://webprod.hc-sc.gc.ca/nhpid-bdipsn/atReq?atid=multi_vitmin_suppl■=eng JECFA 1987: WHO/FAO Joint Expert Committee on Food Additives. Food Additives Monographs. [Consulted 2024 December 10]. 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EC 2009: European Commission. Scientific Committee on Cosmetic Products (SCCP), Health & Consumer Protection, Directorate-General. Clarificaton on the opinions SCCNFP/0653/03 and SCCP/0882/05 on the safety of fluorine compounds in oral hygiene products for children under the age of 6 years. [Accessed 2024 August 29]. Greaves M. Gemmotherapy and Oligotherapy Regenerators of Dying Intoxicated Cells. (US): Xlibris, 2002. Padrazzi P. Fatigue et oligo-éléments. (FR) : Éditions Similia, 1997. Picard H. Utilisation thérapeutique des oligo-éléments, 5 e édition. (FR) : Éditions Maloine, 1986. Sal J., Donadieu Y. Les thérapeutiques naturelles : les oligoéléments. (FR) : Éditions Maloine, 1986. Simon V. Les troubles fonctionnels et leur traitement. (FR): Éditions Maloine, 2002. U.S. Food and Drug Administration, Food and Drugs, Food and Drug Administration Department of Health and Human Services, Drugs for Human Use. Part 369 - Interpretative Statements Re Warnings on Drugs and Devices for Over-The-Counter Sale. [Accessed 2024 August 29]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=369 U.S. Food and Drug Administration, Food and Drugs, Food and Drug Administration Department of Health and Human Services, Drugs for Human Use. Part 355 - Anticaries Drug Products For Over-The-Counter Human Use. [Accessed 2024

August 29]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=355 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-basedPLAform is not possible where reference is made to this monograph. Please use thePDFformat 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 Please refer to Tables 1 and 2 below.

DOSAGE FORM(S)

The acceptable dosage forms are capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.

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-basedPLAform is not possible where reference is made to this monograph. Please use thePDFformat 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

Cautions and warnings 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 containing Aluminium Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have a kidney disorder (JECFA 1987). Products containing Cobalt Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking Vitamin B12 (EVM 2003).Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if you experience gastrointestinal discomfort/disturbances and/or skin rashes. Products providing doses of Selenium ≥ 200 µg per day. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have a history of non-melanoma skin cancer. Contraindication(s) Products containing Cobalt Do not use if you have an iodine deficiency (EVM 2003). Products containing Manganese Do not use if you have tuberculosis or a history of tuberculosis (Padrazzi 1988; Ménétrier 1983). Products containing Manganese and Cobalt Do not use if you have tuberculosis or a history of tuberculosis (Ménétrier 1983). Products containing Zinc and/or Copper Do not

use if you have cancer, tuberculosis or a history of tuberculosis (Padrazzi 1988; Ménétrier 1983). Known adverse reaction(s) Products containing Fluoride When using this product you may experience mottling of the tooth enamel 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.

NON-MEDICINAL INGREDIENTS

Must be chosen from the currentNatural 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 Quality of Natural Health Products Guide.The finished product must comply with the minimum specifications outlined in the currentNHPID. Example of Product Facts: Consult the Guidance Document,Labelling of Natural Health Productsfor more details.

REFERENCES

Brigo, B. Logique thérapeutique des Oligoéléments et des remèdes en lithothérapie. Collection Résurgence. (LU): Marco Pietteur, editor, 1999.EVM 2003: Expert Group on Vitamins and Minerals. Safe Upper Levels for Vitamins and Minerals. May 2003. [Accessed 2024 August 29]. Available from: https://cot.food.gov.uk/sites/default/files/vitmin2003.pdfHealth Canada 2023: Multi-vitamin/mineral supplements monograph. Natural and Non-prescription Health Products Directorate. Ottawa (ON). [Accessed 2024 August 26]. Available from: https://webprod.hc-sc.gc.ca/nhpid-bdipsn/atReq?atid=multi_vitmin_suppl■=engJECFA 1987: WHO/FAO Joint Expert Committee on Food Additives. Food Additives Monographs. [Consulted 2024 December 10]. Available from: https://www.inchem.org/documents/ehc/ehc/ehc194.htmMénétrier J. La médecine des fonctions, deuxième édition. (FR): Hemsi, 1983.Padrazzi P. L'oligothérapie réactionnelle. (FR): Éditions Similia, 1988.Sweetman SC, editor. Martindale: The Complete Drug Reference, 39th edition. Grayslake (IL): Pharmaceutical Press; 2017. References reviewed ANSM 2024: Agence nationale de sécurité du médicament et des produits de santé. [Accessed 2024 August 29]. Available from: https://ansm.sante.fr/ASHP 2005: American Society of Health-System Pharmacists. American Hospital Formulary Service (AHFS) Drug Information. Philadelphia (PA): Lippincott Williams and Wilkins; 2005.Chappuis P. Favier A.Les oligoéléments en nutrition et en thérapeutique.(FR): Lavoisier, 1995.Douart, JP.L'Oligothérapie en pathologie fonctionnelle: Données scientifiques et cliniques.(FR):Éditons Maloine, 1994.Dupouy A.Oligothérapie: Précis de Clinique et de thérapeutique. (FR): Éditions Maloine, 1988.EC 2009: European Commission. Scientific Committee on Cosmetic Products (SCCP), Health & Consumer Protection, Directorate-General. Clarificaton on the opinions SCCNFP/0653/03 and SCCP/0882/05 on the safety of fluorine compounds in oral hygiene products for children under the age of 6 years. [Accessed 2024 August 29].Greaves M. Gemmotherapy and Oligotherapy Regenerators of Dying Intoxicated Cells. (US): Xlibris, 2002.Padrazzi P.Fatigue et oligo-éléments. (FR) : ÉditionsSimilia, 1997.Picard H.Utilisation thérapeutique des oligo-éléments,

5eédition.(FR) :ÉditionsMaloine, 1986.Sal J., Donadieu Y.Les thérapeutiques naturelles : les oligoéléments. (FR) : ÉditionsMaloine, 1986.Simon V.Les troubles fonctionnels et leur traitement. (FR): ÉditionsMaloine, 2002.U.S. Food and Drug Administration, Food and Drugs, Food and Drug Administration Department of Health and Human Services, Drugs for Human Use. Part 369 - Interpretative Statements Re Warnings on Drugs and Devices for Over-The-Counter Sale. [Accessed 2024 August 29]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=369U.S. Food and Drug Administration, Food and Drugs, Food and Drug Administration Department of Health and Human Services, Drugs for Human Use. Part 355 - Anticaries Drug Products For Over-The-Counter Human Use. [Accessed 2024 August 29]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=355

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

name(s)	Common name(s)	Source ingredient(s)	Maximum quantity per dosag
ese;Cobalt	Manganese;Cobalt	Manganese gluconate;Cobalt gluconate	72.872.6
ese;Copper;Cobalt	Manganese;Copper;Cobalt	Manganese gluconate;Copper gluconate;Cobalt gluconate	72.872.672.8
ese;Copper	Manganese;Copper	Manganese gluconate;Copper gluconate;	72.672.6
lickel	Cobalt;Nickel	Cobalt gluconateNickel gluconate;	72.672.6
Zinc	Copper;Zinc	Coppergluconate;Zinc gluconate	72.667.4
lickel;Zinc	Cobalt;Nickel;Zinc	Cobalt gluconate;Nickel gluconate;Zinc gluconate	72.672.667.4
Gold;Silver	Copper;Gold;Silver	Copper gluconate;Gold elemental;Silver gluconate	31.2250
Gold;Silver	Copper;Gold;Silver	Copper gluconate;Gold elemental;Silver gluconate	631.421.36
Gold;Silver	Copper;Gold;Silver	Copper gluconate;Gold elemental;Silver gluconate	5000.27.4