

Gemmotherapy

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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 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 - part(s)
<i>Abies alba</i>	Silver fir Buds; Young shoots	<i>Abies balsamea</i>
<i>Balsam fir Buds; Young shoots</i>	<i>Acer campestre</i>	Field maple; Hedge maple Buds
<i>Aesculus hippocastanum</i>	Horse chestnut Buds	<i>Alnus glutinosa</i>
Alder; Black alder; European alder Buds	<i>Alnus incana</i>	Mountain alder Buds
<i>Ampelopsis veitchii</i>	Boston ivy; Virgin vine; Wild woodvine	Young shoots
<i>Betula alba</i> ; <i>Betula pubescens</i>	White birch; Downy birch Buds; Catkin; Inner bark of stems/roots; Radicles; Sap	<i>Betula verrucosa</i> ; <i>Betula pendula</i>
European white birch; Silver birch Buds; Seeds; Sap	<i>Buxus sempervirens</i>	Boxwood Young shoots
<i>Calluna vulgaris</i>	Heather Young shoots	<i>Carpinus betulus</i>
Hornbeam Buds	<i>Castanea vesca/sativa</i>	Chestnut; Sweet chestnut; Spanish chestnut Buds
<i>Cedrus libani</i>	Cedar of Lebanon Young shoot	<i>Cercis siliquastrum</i>
Judas tree Buds	<i>Citrus limonum</i>	Lemon; Lemon tree Stem bark; Young shoot
<i>Cornus sanguinea</i>	Dogwood Buds	<i>Corylus avellana</i>
Hazel Buds	<i>Crataegus oxyacantha/laevigata</i>	Hawthorn Young shoot; Buds
<i>Equisetum arvense</i>	Horsetail Young shoot	<i>Fagus sylvatica</i>
European beech; Common beech; Beech Buds	<i>Ficus carica</i>	Fig Buds
<i>Fraxinus excelsior</i>	Ash Buds	<i>Ginkgo biloba</i>
Ginkgo Buds; Leaves	<i>Hippophae rhamnoides</i>	Sea buckthorn Buds
<i>Ilex aquifolium</i>	English Holly; Holly Young shoots	<i>Juglans regia</i>
English walnut; Walnut; Walnut tree Buds	<i>Juniperus communis</i>	Common juniper; Juniper Young shoots
<i>Ligustrum vulgare</i>	Privet Young shoots	<i>Lonicera nigra</i>
Honeysuckle Young shoots	<i>Malus sylvestris</i>	Crab apple; European crab apple Buds
<i>Morus nigra</i>	Black Mulberry Buds	<i>Olea europaea</i>
Olive Young shoots	<i>Pinus montana/mugo</i>	Mountain pine Buds
<i>Platanus orientalis</i>	Oriental planetree Buds	<i>Populus nigra</i>
Black poplar Buds	<i>Prunus amygdalus/dulcis</i>	Almond; Sweet almond Buds; Root bark (rootlet)
<i>Quercus robur/pedunculata</i>	English oak; Pedunculate oak Buds	<i>Ribes nigrum</i>
Black currant Buds	<i>Rosa canina</i>	Dog rose Young shoots
<i>Rosmarinus officinalis</i>	Rosemary Young shoots	<i>Rubus fruticosus</i>
Blackberry; Bramble Young shoots	<i>Rubus idaeus</i>	Raspberry Young shoots
<i>Sambucus nigra</i>	Black elder Buds	<i>Salix alba</i>
White willow Buds; Catkins	<i>Secale cereale</i>	Rye Root bark (rootlet)
<i>Sequoia gigantea</i>	Giant sequoia; Giant Redwood Young shoots	<i>Sorbus domestica</i>
Servicetree; Rowan tree Buds	<i>Syringa vulgaris</i>	Lilac Buds
<i>Tamarix gallica</i>	Tamarisk Young shoots	<i>Tilia tomentosa</i>
Silver linden; Linden tree Buds	<i>Ulmus campestris/minor</i>	European field elm; Elm Buds
<i>Vaccinium myrtillus</i>	Bilberry; European blueberry Buds; Young shoots	<i>Vaccinium vitis-idaea</i>
Ligonberry; Cowberry; Wine berry Young shoots	<i>Viburnum lantana</i>	Wayfaring tree Buds
<i>Vinca minor</i>	Common periwinkle; Lesser periwinkle Young shoots	<i>Viscum album</i>
European mistletoe; Mistletoe Young shoots	<i>Vitis vinifera</i>	Grape; Grape vine Buds
<i>Zea mays</i>	Corn; Maize Root bark (rootlet)	Route of administration

Oral 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: capsule, liquid. Use(s) or Purpose(s) Gemmotherapy preparation/remedy/medicine Dose Subpopulation(s) Adults 18 years and older Quantity(ies) Capsule; Liquid Medicinal ingredients with extract ratio 1:20 Maximum 37.5 mg Quantity Crude Equivalent (QCE) 1 of medicinal ingredient per day. Products containing a single medicinal ingredient Maximum 2.5 mg QCE of medicinal ingredient per capsule/drop. Products containing multiple medicinal ingredients 2

Maximum 2.5 mg QCE of medicinal ingredients per capsule/drop (Refer to Appendix 1 for examples). Medicinal ingredients with extract ratio 1:200 Maximum 56.25 mg QCE of medicinal ingredient per day. Products containing a single medicinal ingredient Maximum 0.25 mg QCE of medicinal ingredient per capsule/drop. Products containing multiple medicinal ingredients 2 Maximum 0.25 mg QCE of medicinal ingredients per capsule/drop (Refer to Appendix 1 for examples). Notes: 1 Quantity Crude Equivalent always refers to the Fresh source material in this monograph. 2 The quantity per capsule/drop and the QCE of each medicinal ingredient will depend on the number of medicinal ingredients and their proportions in the product. Liquid only Betula (alba/pubescens/verrucosa/pendula) sap Maximum 0.05 ml of fresh sap per drop; And Maximum 300 drops or 15 ml or 1 table spoon per day. Method(s) of preparation The method of preparation must be one of the following (see Notes below for alcohol-free macerate option 1): PhF 2 glycerine macerate Ph. Eur. 3 Notes: 1 To obtain an alcohol-free glycerin macerate, the mixture is heated to a temperature below 50°C, until the alcohol has evaporated. 2 French Pharmacopoeia 3 European Pharmacopoeia 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 Betula (alba/pubescens/verrucosa/pendula)sap When using this product drink plenty of water. 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 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. 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. 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 Andrianne P. La gemmothérapie: Médecine des bourgeons. Éditions Amyris, 2002. Andrianne P. Guide de Gémmothérapie, Éditions Amyris, 2008. Andrianne P. Bio Info. Éditions Changer d'R. No 83. Greaves M. Gemmotherapy and Oligotherapy Regenerators of Dying Intoxicated Cells. (US): Xlibris, 2008. Goetz P. Quelques éléments pratiques de gemmothérapie. Phytothérapie 2006;2:83-86. Fédération Européenne d'Herboristerie. 2024. [Accessed 2024 August 8] Available from: <http://www.feh.be> Henry P. Gemmothérapie : Thérapeutique par les extraits embryonnaires végétaux. St.Norbert Westerlo (BE), 2008. Rozenccwajg J. Dynamic Gemmotherapy: Integrative Embryonie Phytotherapy, 2008. Téttau M. Nouvelles cliniques de gemmothérapie. Éditions Similia, 1991. Appendix I Quantity per capsule/drop and quantity crude equivalent (QCE) for medicinal ingredients in various sample products based on their proportions Example Medicinal ingredients in the product Proportion of each ingredient in the product (%) QCE (mg) per capsule/drop for ratio 1:20 (maximum 2.5 mg) QCE (mg) per capsule/drop for ratio 1:200 (maximum 0.25 mg) 1 Betula alba 100 2.5 0.25 2 Betula alba Juglans regia 50 50 1.25 1.25 0.125 0.125 3 Alnus incana Lonicera nigra 75 25 1.875 0.625 0.1875 0.0625 4 Abies alba Malus sylvestris Zea mays 33.3 33.3 33.3 0.83 0.83 0.83 0.083 0.083 0.083 5 Citrus limonum Rosa canina Vitis vinifera 60 30 10 1.5 0.75 0.25 0.15 0.075 0.025 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 ingredients

Proper name(s)	Common name(s)	Source material - part(s)
Abies alba	Silver fir	Buds; Young shoots
Abies balsamea	Balsam fir	Buds; Young shoots
Acer campestre	Field maple; Hedge maple	Buds
Aesculus hippocastanum	Horse chestnut	Buds
Alnus glutinosa	Alder; Black alder; European alder	Buds
Alnus incana	Mountain alder	Buds
Ampelopsis veitchii	Boston ivy; Virgin vine; Wild woodvine	Young shoots
Betula alba; Betula pubescens	White birch; Downy birch	Buds; Catkin; Inner bark of stems/roots; Radicles; Sap
Betula verrucosa; Betula pendula	European white birch; Silver birch	Buds; Seeds; Sap
Buxus sempervirens	Boxwood	Young shoots
Calluna vulgaris	Heather	Young shoots
Carpinus betulus	Hornbeam	Buds
Castanea vesca/sativa	Chestnut; Sweet chestnut; Spanish chestnut	Buds
Cedrus libani	Cedar of Lebanon	Young shoot
Cercis siliquastrum	Judas tree	Buds
Citrus limonum	Lemon; Lemon tree	Stem bark; Young shoot
Cornus sanguinea	Dogwood	Buds
Corylus avellana	Hazel	Buds
Crataegus oxyacantha/laevigata	Hawthorn	Young shoot; Buds
Equisetum arvense	Horsetail	Young shoot
Fagus sylvatica	European beech; Common beech; Beech	Buds
Ficus carica	Fig	Buds
Fraxinus excelsior	Ash	Buds
Ginkgo biloba	Ginkgo	Buds; Leaves
Hippophae rhamnoides	Sea buckthorn	Buds
Ilex aquifolium	English Holly; Holly	Young shoots
Juglans regia	English walnut; Walnut; Walnut tree	Buds
Juniperus communis	Common juniper; Juniper	Young shoots
Ligustrum vulgare	Privet	Young shoots
Lonicera nigra	Honeysuckle	Young shoots
Malus sylvestris	Crab apple; European crab apple	Buds
Morus nigra	Black Mulberry	Buds
Olea europaea	Olive	Young shoots
Pinus montana/mugo	Mountain pine	Buds
Platanus orientalis	Oriental planetree	Buds
Populus nigra	Black poplar	Buds
Prunus amygdalus/dulcis	Almond; Sweet almond	Buds; Root bark (rootlet)
Quercus robur/pedunculata	English oak; Pedunculate oak	Buds
Ribes nigrum	Black currant	Buds
Rosa canina	Dog rose	Young shoots
Rosmarinus officinalis	Rosemary	Young shoots
Rubus fruticosus	Blackberry; Bramble	Young shoots
Rubus idaeus	Raspberry	Young shoots
Sambucus nigra	Black elder	Buds
Salix alba	White willow	Buds; Catkins
Secale cereale	Rye	Root bark (rootlet)
Sequoia gigantea	Giant sequoia; Giant Redwood	Young shoots
Sorbus domestica	Servicetree; Rowan tree	Buds
Syringa vulgaris	Lilac	Buds
Tamarix gallica	Tamarisk	Young shoots
Tilia tomentosa	Silver linden; Linden tree	Buds
Ulmus campestris/minor	European field elm; Elm	Buds
Vaccinium myrtillus	Bilberry; European blueberry	Buds; Young shoots
Vaccinium vitis-idaea	Ligonberry; Cowberry; Wine berry	Young shoots
Viburnum lantana	Wayfaring tree	Buds
Vinca minor	Common periwinkle; Lesser periwinkle	Young shoots
Viscum album	European mistletoe; Mistletoe	Young shoots
Vitis vinifera	Grape; Grape vine	Buds
Zea mays	Corn; Maize	Root bark (rootlet)

Route of administration Oral

DOSAGE FORM(S)

The acceptable dosage forms are: capsule, liquid.

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) 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.

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.

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. Example of Product Facts: Consult the Guidance Document, Labelling of Natural Health Products for 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. 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 Andrianne P. La gemmothérapie: Médecine des bourgeons. Éditions Amyris, 2002. Andrianne P. Guide de Gémmothérapie, Éditions Amyris, 2008. Andrianne P. Bio Info. Éditions Changer d'R. No 83. Greaves M. Gemmotherapy and Oligotherapy Regenerators of Dying Intoxicated Cells. (US): Xlibris, 2008. Goetz P. Quelques éléments pratiques de gemmothérapie. Phytothérapie 2006;2:83-86. Fédération Européenne d'Herboristerie. 2024. [Accessed 2024 August 8] Available from: <http://www.feh.be> Henry P. Gemmothérapie : Thérapeutique par les extraits embryonnaires végétaux. St. Norbert Westerlo (BE), 2008. Rozencwajg J. Dynamic Gemmotherapy: Integrative Embryonic Phytotherapy, 2008. Tétou M. Nouvelles cliniques de gemmothérapie. Éditions Similia, 1991. Appendix I Quantity per capsule/drop and quantity crude equivalent (QCE) for medicinal ingredients in various sample products based on their proportions Example Medicinal ingredients in the product Proportion of each ingredient in the product (%) QCE (mg) per capsule/drop for ratio 1:20 (maximum 2.5 mg) QCE (mg) per capsule/drop for ratio 1:200 (maximum 0.25 mg)

1 Betula alba	1002.50.252	Betula alba	Juglans regia	50501.251.250.1250.1253	Alnus incana	Lonicera nigra	75251.8750.6250.18750.06254	Abies alba	Malus sylvestris	Zea mays	33.333.333.30.830.830.830.0830.0830.0835	Citrus limonum	Rosa canina	Vitis vinifera	6030101.50.750.250.150.0750.025
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Aesculus hippocastanum	Horse chestnut	Buds
Alnus glutinosa	Alder;Black alder;European alder	Buds
Alnus incana	Mountain alder	Buds
Ampelopsis veitchii	Boston ivy;Virgin vine;Wild woodvine	Young shoots
Betula alba;Betula pubescens	White birch;Downy birch	Buds;Catkin;Inner bark of stems/roots;Radicles;Sap
Betula verrucosa;Betula pendula	European white birch;Silver birch	Buds;Seeds;Sap
Buxus sempervirens	Boxwood	Young shoots
Calluna vulgaris	Heather	Young shoots
Carpinus betulus	Hornbeam	Buds
Castanea vesca/sativa	Chestnut;Sweet chestnut;Spanish chestnut	Buds
Cedrus libani	Cedar of Lebanon	Young shoot
Cercis siliquastrum	Judas tree	Buds
Citrus limonum	Lemon;Lemon tree	Stem bark;Young shoot
Cornus sanguinea	Dogwood	Buds
Corylus avellana	Hazel	Buds
Crataegus oxyacantha/laevigata	Hawthorn	Young shoot;Buds
Equisetum arvense	Horsetail	Young shoot
Fagus sylvatica	European beech;Common beech;Beech	Buds
Ficus carica	Fig	Buds
Fraxinus excelsior	Ash	Buds
Ginkgo biloba	Ginkgo	Buds;Leaves
Hippophae rhamnoides	Sea buckthorn	Buds
Ilex aquifolium	English Holly;Holly	Young shoots
Juglans regia	English walnut;Walnut;Walnut tree	Buds
Juniperus communis	Common juniper;Juniper	Young shoots
Ligustrum vulgare	Privet	Young shoots
Lonicera nigra	Honeysuckle	Young shoots
Malus sylvestris	Crab apple;European crab apple	Buds
Morus nigra	Black Mulberry	Buds
Olea europaea	Olive	Young shoots
Pinus montana/mugo	Mountain pine	Buds
Platanus orientalis	Oriental planetree	Buds
Populus nigra	Black poplar	Buds
Prunus amygdalus/dulcis	Almond;Sweet almond	Buds;Root bark (rootlet)
Quercus robur/pedunculata	English oak; Pedunculate oak	Buds
Ribes nigrum	Black currant	Buds
Rosa canina	Dog rose	Young shoots

Rosmarinus officinalis	Rosemary	Young shoots
Rubus fruticosus	Blackberry;Bramble	Young shoots
Rubus idaeus	Raspberry	Young shoots
Sambucus nigra	Black elder	Buds
Salix alba	White willow	Buds; Catkins
Secale cereale	Rye	Root bark (rootlet)
Sequoia gigantea	Giant sequoia;Giant Redwood	Young shoots
Sorbus domestica	Servicetree;Rowan tree	Buds
Syringa vulgaris	Lilac	Buds
Tamarix gallica	Tamarisk	Young shoots
Tilia tomentosa	Silver linden;Linden tree	Buds
Ulmus campestris/minor	European field elm;Elm	Buds
Vaccinium myrtillus	Bilberry;European blueberry	Buds;Young shoots
Vaccinium vitis-idaea	Ligonberry;Cowberry;Wine berry	Young shoots
Viburnum lantana	Wayfaring tree	Buds
Vinca minor	Common periwinkle; Lesser periwinkle	Young shoots
Viscum album	European mistletoe;Mistletoe	Young shoots
Vitis vinifera	Grape;Grape vine	Buds
Zea mays	Corn;Maize	Root bark (rootlet)

Principal ingredients in the product	Proportion of each ingredient in the product (%)	Quantity (mg) per capsule/drop for ratio 1:20	Quantity (mg) per capsule/drop for ratio 1:25
Salix alba	100	2.5	0.25
Salix albaJuglans regia	5050	1.251.25	0.1250.125
Salix albaLonicera nigra	7525	1.8750.625	0.18750.0625
Salix albaMalus sylvestrisZea mays	33.333.333.3	0.830.830.83	0.0830.0830.083
Salix albaLimonumRosa caninaVitis vinifera	603010	1.50.750.25	0.150.0750.025