

## NATURAL HEALTH PRODUCT

### GEMMOTHERAPY

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)

**Table 1** Products may contain one or more of the following ingredients

Proper name(s)	Common name(s)	Source material(s)
<i>Abies alba</i>	Silver fir	Buds; Young shoots
<i>Abies balsamea</i>	Balsam fir	Buds; Young shoots
<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



Proper name(s)	Common name(s)	Source material(s)
<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 o; 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



Proper name(s)	Common name(s)	Source material(s)
<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(s) of administration

Oral

### Dosage form(s)

- ▶ The acceptable pharmaceutical dosage forms are liquids only.
- ▶ This monograph is not intended to include dosage forms such as beverages.

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

Gemmotherapy preparation/remedy/medicine

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

### Subpopulation

Adults ( ≥ 18 years)

### Quantity(ies)

*Medicinal ingredients with extract ratio 1:20*

Maximum 37.5 mg QCE of medicinal ingredient per day.

Products containing a single medicinal ingredient:

Maximum 2.5 mg Quantity Crude Equivalent (QCE) of medicinal ingredient per drop.

Products containing multiple medicinal ingredients\*:  
Maximum 2.5 mg QCE of medicinal ingredients per 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 drop.

Products containing multiple medicinal ingredients\*:  
Maximum 0.25 mg QCE of medicinal ingredients per drop (Refer to Appendix 1 for examples).

*Betula (alba/pubescens/verrucosa/pendula) sap*

Maximum 300 drops or 15 ml or 1 table spoon per day.  
Maximum 0.05 ml of fresh sap per drop.

\*The quantity per drop and the quantity crude equivalent (QCE) of each medicinal ingredient will depend on the number of medicinal ingredients and their proportions in the product. Please refer to Appendix II for examples.

### **Method of preparation**

The method of preparation must be one of the following:

- ▶ PhF glycerine macerate
- ▶ Ph. Eur.

### **Directions for use**

*All products*

Take as directed by a health care practitioner.

*Products containing Betula (alba/pubescens/verrucosa/pendula) sap*

Drink plenty of water, when using this product.

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

No statement required.

**Risk information** Statement(s) to the effect of**Cautions and warnings**

- ▶ If symptoms persist or worsen, consult a health care practitioner.
- ▶ If you are pregnant or breastfeeding, consult a health care practitioner prior to use.

**Contraindications**

No statement required.

**Known adverse reactions**

No statement required.

**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).

**References reviewed**

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Andrienne P. *Bio Info*. Éditions Changer d'R. No 83.

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## Appendix I

### Quantity per 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 drop for ratio 1:20 (maximum 2.5 mg)	QCE (mg) per drop for ratio 1:200 (maximum 0.25 mg)
1	<i>Betula alba</i>	100	2.5	0.25
2	<i>Betula alba</i> <i>Juglans regia</i>	50 50	1.25 1.25	0.125 0.125
3	<i>Alnus incana</i> <i>Lonicera nigra</i>	75 25	1.875 0.625	0.1875 0.0625
4	<i>Abies alba</i> <i>Malus sylvestris</i> <i>Zea mays</i>	33.3 33.3 33.3	0.83 0.83 0.83	0.083 0.083 0.083
5	<i>Citrus limonum</i> <i>Rosa canina</i> <i>Vitis vinifera</i>	60 30 10	1.5 0.75 0.25	0.15 0.075 0.025

## Appendix II

**Quantity per drop and quantity crude equivalent (QCE) for various proportions of medicinal ingredients based on product with 1 drop = 0.05mL**

Proportion of medicinal ingredient in the product (%)	Quantity per drop (mL)	Quantity crude equivalent for ratio 1:20 (mg)	Quantity crude equivalent for ratio 1:200 (mg)
10	0.005	0.25	0.025
20	0.01	0.5	0.05
30	0.015	0.75	0.075
40	0.02	1.0	0.1
50	0.025	1.25	0.125
60	0.03	1.5	0.15
70	0.035	1.75	0.175
80	0.04	2.0	0.2
90	0.045	2.25	0.225
100	0.05	2.5	0.25

**Note:** For proportions not represented in this table, the following calculations are required to determine the quantity per dosage unit and the quantity crude equivalent.

Calculations of QCE of medicinal ingredients (MIs):

QCE (1:20) of MI = Proportion of MI in product (in %) x QCE of all MIs (maximum 2.5 mg)

QCE (1:200) of MI = Proportion of MI in product (in %) x QCE of all MIs (maximum 0.25 mg)