# abnobaVISCUM® Summary of Product Characteristics (all products)

## 1 Name of the medicinal product

**abnobaVISCUM Abietis D 6**
**abnobaVISCUM Abietis D 10**
**abnobaVISCUM Abietis D 20**
**abnobaVISCUM Abietis D 30**

Liquid dilution for injection

Active substance:
Viscum album Abietis ex herba recente col. D 6/D 10/D 20/D 30

**abnobaVISCUM Abietis 20 mg**
**abnobaVISCUM Abietis 2 mg**
**abnobaVISCUM Abietis 0.2 mg**
**abnobaVISCUM Abietis 0.02 mg**

Solution for injection

Active substance:
Extract of fresh fir mistletoe herb

**abnobaVISCUM Aceris D 6**
**abnobaVISCUM Aceris D 10**
**abnobaVISCUM Aceris D 20**
**abnobaVISCUM Aceris D 30**

Liquid dilution for injection

Active substance:
Viscum album Aceris ex herba recente col. D 6/D 10/D 20/D 30

**abnobaVISCUM Aceris 20 mg**
**abnobaVISCUM Aceris 2 mg**
**abnobaVISCUM Aceris 0.2 mg**
**abnobaVISCUM Aceris 0.02 mg**

Solution for injection

Active substance:
Extract of fresh maple mistletoe herb

**abnobaVISCUM Amygdali D 6**
**abnobaVISCUM Amygdali D 10**
**abnobaVISCUM Amygdali D 20**
**abnobaVISCUM Amygdali D 30**

Liquid dilution for injection

Active substance:
Viscum album Amygdali ex herba recente col. D 6/D 10/D 20/D 30

**abnobaVISCUM Amygdali 20 mg**
**abnobaVISCUM Amygdali 2 mg**
**abnobaVISCUM Amygdali 0.2 mg**
**abnobaVISCUM Amygdali 0.02 mg**

Solution for injection

Active substance:
Extract of fresh almond mistletoe herb

**abnobaVISCUM Betulae D 6**
**abnobaVISCUM Betulae D 10**
**abnobaVISCUM Betulae D 20**
**abnobaVISCUM Betulae D 30**

Liquid dilution for injection

Active substance:
Viscum album Betulae ex herba recente col. D 6/D 10/D 20/D 30

**abnobaVISCUM Betulae 20 mg**
**abnobaVISCUM Betulae 2 mg**
**abnobaVISCUM Betulae 0.2 mg**
**abnobaVISCUM Betulae 0.02 mg**

Solution for injection

Active substance:
Extract of fresh birch mistletoe herb

**abnobaVISCUM Crataegi D 6**
**abnobaVISCUM Crataegi D 10**
**abnobaVISCUM Crataegi D 20**
**abnobaVISCUM Crataegi D 30**

Liquid dilution for injection

Active substance:
Viscum album Crataegi ex herba recente col. D 6/D 10/D 20/D 30

**abnobaVISCUM Crataegi 20 mg**
**abnobaVISCUM Crataegi 2 mg**
**abnobaVISCUM Crataegi 0.2 mg**
**abnobaVISCUM Crataegi 0.02 mg**

Solution for injection

Active substance:
Extract of fresh hawthorn mistletoe herb

**abnobaVISCUM Fraxini D 6**
**abnobaVISCUM Fraxini D 10**
**abnobaVISCUM Fraxini D 20**
**abnobaVISCUM Fraxini D 30**

Liquid dilution for injection

Active substance:
Viscum album Fraxini ex herba recente col. D 6/D 10/D 20/D 30

**abnobaVISCUM Fraxini 20 mg**
**abnobaVISCUM Fraxini 2 mg**
**abnobaVISCUM Fraxini 0.2 mg**
**abnobaVISCUM Fraxini 0.02 mg**

Solution for injection

Active substance:
Extract of fresh ash mistletoe herb

**abnobaVISCUM Mali D 6**
**abnobaVISCUM Mali D 10**
**abnobaVISCUM Mali D 20**
**abnobaVISCUM Mali D 30**

Liquid dilution for injection

Active substance:
Viscum album Mali ex herba recente col. D 6/D 10/D 20/D 30

**abnobaVISCUM Mali 20 mg**
**abnobaVISCUM Mali 2 mg**
**abnobaVISCUM Mali 0.2 mg**
**abnobaVISCUM Mali 0.02 mg**

Solution for injection

Active substance:
Extract of fresh apple mistletoe herb

**abnobaVISCUM Pini D 6**
**abnobaVISCUM Pini D 10**
**abnobaVISCUM Pini D 20**
**abnobaVISCUM Pini D 30**

Liquid dilution for injection

Active substance:
Viscum album Pini ex herba recente col. D 6/D 10/D 20/D 30

**abnobaVISCUM Pini 20 mg**
**abnobaVISCUM Pini 2 mg**
**abnobaVISCUM Pini 0.2 mg**
**abnobaVISCUM Pini 0.02 mg**

Solution for injection

Active substance:
Extract of fresh pine mistletoe herb

**abnobaVISCUM Quercus D 6**
**abnobaVISCUM Quercus D 10**
**abnobaVISCUM Quercus D 20**
**abnobaVISCUM Quercus D 30**

Liquid dilution for injection

Active substance:
Viscum album Quercus ex herba recente col. D 6/D 10/D 20/D 30

**abnobaVISCUM Quercus 20 mg**
**abnobaVISCUM Quercus 2 mg**
**abnobaVISCUM Quercus 0.2 mg**
**abnobaVISCUM Quercus 0.02 mg**

Solution for injection

Active substance:
Extract of fresh oak mistletoe herb

## 2 Qualitative and quantitative composition

| Name of the medicinal product | 1 ampoule of 1 ml contains<br>Active substance: |
|---|---|
| **abnobaVISCUM Abietis D 6/D 10/D 20/D 30** | Viscum album Abietis ex herba recente col. Dil.<br>D 6/D 10/D 20/D 30 (GHP [German Homeopathic Pharmacopoeia], V. 32) 1 ml |
| **abnobaVISCUM Abietis 20 mg/2 mg/0.2 mg/ 0.02 mg** | Extract of fresh fir mistletoe herb<br>(plant to extract = 1:50) 1 ml/0.1 ml/0.01 ml/0.001 ml<br>Extractant:<br>Sodium monohydrogen phosphate 2 $H_2O$, ascorbic acid, water for injection (2.03 : 0.34 : 97.63) |
| **abnobaVISCUM Aceris D 6/D 10/D 20/D 30** | Viscum album Aceris ex herba recente col. Dil.<br>D 6/D 10/D 20/D 30 (GHP [German Homeopathic Pharmacopoeia], V. 32) 1ml |
| **abnobaVISCUM Aceris 20 mg/2 mg/0.2 mg/ 0.02 mg** | Extract of fresh maple mistletoe herb<br>(plant to extract = 1:50) 1 ml/0.1 ml/0.01 ml/0.001 ml<br>Extractant:<br>Sodium monohydrogen phosphate 2 $H_2O$, ascorbic acid, water for injection (2.03 : 0.34 : 97.63) |
| **abnobaVISCUM Amygdali D 6/D 10/D 20/D 30** | Viscum album Amygdali ex herba recente col. Dil.<br>D 6/D 10/D 20/D 30 (GHP [German Homeopathic Pharmacopoeia], V. 32) 1ml |
| **abnobaVISCUM Amygdali 20 mg/2 mg/0.2 mg/ 0.02 mg** | Extract of fresh almond mistletoe herb<br>(plant to extract = 1:50) 1 ml/0.1 ml/0.01 ml/0.001 ml<br>Extractant:<br>Sodium monoihydrogen phosphate 2 $H_2O$, ascorbic acid, water for injection (2.03 : 0.34 : 97.63) |
| **abnobaVISCUM Betulae D 6/D 10/D 20/D 30** | Viscum album Betulae ex herba recente col. Dil.<br>D 6/D 10/D 20/D 30 (GHP [German Homeopathic Pharmacopoeia], V. 32) 1ml |
| **abnobaVISCUM Betulae 20 mg/2 mg/0.2 mg/ 0.02 mg** | Extract of fresh birch mistletoe herb<br>(plant to extract = 1:50) 1 ml/0.1 ml/0.01 ml/0.001 ml<br>Extractant:<br>Sodium monohydrogen phosphate 2 $H_2O$, ascorbic acid, water for injection (2.03 : 0.34 : 97.63) |
| **abnobaVISCUM Crataegi D 6/D 10/D 20/D 30** | Viscum album Crataegi ex herba recente col. Dil.<br>D 6/D 10/D 20/D 30 (GHP [German Homeopathic Pharmacopoeia], V. 32) 1ml |
| **abnobaVISCUM Crataegi 20 mg/2 mg/0.2 mg/ 0.02 mg** | Extract of fresh hawthorn mistletoe herb<br>(plant to extract = 1:50) 1 ml/0.1 ml/0.01 ml/0.001 ml<br>Extractant:<br>Sodium monohydrogen phosphate 2 $H_2O$, ascorbic acid, water for injection (2.03 : 0.34 : 97.63) |
| **abnobaVISCUM Fraxini D 6/D 10/D 20/D 30** | Viscum album Fraxini ex herba recente col. Dil.<br>D 6/D 10/D 20/D 30 (GHP [German Homeopathic Pharmacopoeia], V. 32) 1ml |
| **abnobaVISCUM Fraxini 20 mg/2 mg/0.2 mg/ 0.02 mg** | Extract of fresh ash mistletoe herb<br>(plant to extract = 1:50) 1 ml/0.1 ml/0.01 ml/0.001 ml<br>Extractant:<br>Sodium monohydrogen phosphate 2 $H_2O$, ascorbic acid, water for injection (2.03 : 0.34 : 97.63) |

| | |
|---|---|
| **abnobaVISCUM Mali D 6/D 10/D 20/D 30** | Viscum album Mali ex herba recente col. Dil. D 6/D 10/D 20/D 30 (GHP [German Homeopathic Pharmacopoeia], V. 32) 1ml |
| **abnobaVISCUM Mali 20 mg/2 mg/0.2 mg/ 0.02 mg** | Extract of fresh apple mistletoe herb (plant to extract = 1:50) 1 ml/0.1 ml/0.01 ml/0.001 ml Extractant: Sodium monohydrogen phosphate 2 $H_2O$, ascorbic acid, water for injection (2.03 : 0.34 : 97.63) |
| **abnobaVISCUM Pini D 6/D 10/D 20/D 30** | Viscum album Pini ex herba recente col. Dil. D 6/D 10/D 20/D 30 (GHP [German Homeopathic Pharmacopoeia], V. 32) 1ml |
| **abnobaVISCUM Pini 20 mg/2 mg/0.2 mg/ 0.02 mg** | Extract of fresh pine mistletoe herb (plant to extract = 1:50) 1 ml/0.1 ml/0.01 ml/0.001 ml Extractant: Sodium monohydrogen phosphate 2 $H_2O$, ascorbic acid, water for injection (2.03 : 0.34 : 97.63) |
| **abnobaVISCUM Quercus D 6/D 10/D 20/D 30** | Viscum album Quercus ex herba recente col. Dil. D 6/D 10/D 20/D 30 (GHP [German Homeopathic Pharmacopoeia], V. 32) 1ml |
| **abnobaVISCUM Quercus 20 mg/2 mg/0.2 mg/ 0.02 mg** | Extract of fresh oak mistletoe herb (plant to extract = 1:50) 1 ml/0.1 ml/0.01 ml/0.001 ml Extractant: Sodium monohydrogen phosphate 2 $H_2O$, ascorbic acid, water for injection (2.03 : 0.34 : 97.63) |

**For the strengths 20 mg/2 mg/0.2 mg/0.02 mg:**

The strength in mg indicates the quantity of fresh plant material used for the manufacture of 1 ampoule of abnobaVISCUM from the respective host tree.

Example: “abnobaVISCUM Abietis 20 mg” contains an extract of 20 mg fresh fir mistletoe herb in one ampoule.

For a full list of excipients, see section 6.1.

## 3 Pharmaceutical form

**Strengths of 20 mg/2 mg/0.2 mg/0.02 mg:**

Solution for injection

**Potency levels D 6/D 10/D 20/D 30:**

Liquid dilution for injection

# 4 Clinical particulars

## 4.1 Therapeutic indications

Therapeutic indications according to the anthroposophical understanding of man and nature. These include, in adults, stimulation of the forming and integrative forces for the elimination and re-assimilation of growth processes which have become independent, e.g.:

- in malignant tumor diseases, also with accompanying disorders of the hematopoietic organs
- as prophylaxis against relapse following tumor surgery
- in defined precancerous conditions
- in benign tumor diseases

## 4.2 Posology, method and duration of administration

Initiation phase

**Posology and frequency of use (for all abnobaVISCUM preparations)**

Unless otherwise prescribed, the usual dosage is 1 ml solution for injection of the given strength or potency level. Treatment should be initiated with the 0.02 mg strength (for the strengths 0.02 mg, 0.2 mg, 2 mg, 20 mg and potency level D 6) three times weekly. Then the dose is gradually increased until the optimal dose is achieved.

The potency levels D 10 - D 30 are to be used according to individual diagnosis.

The optimal concentration or dose must be individually determined. According to current knowledge, it is important to watch for the following reactions, which may occur individually or in combination.

a) Change in the subjective sense of well-being

On the day of injection, possible fatigue, shivering, general malaise, headache and transient dizziness are not signs of intolerance; moreover, these signs indicate an effective (and possibly excessive) dosing. However, if such symptoms have not subsided by the following day or exceed a tolerable level, the strength or dose should be reduced.

An improvement in general state of health (increase in appetite and body weight, normalization of sleep, sensation of warmth and performance) and mental state (improvement in mood, increase in courage to face life and ability to show initiative) as well as alleviation of pain conditions show that dosing is in a therapeutically optimal range.

b) Temperature response

Temperature reactions occur in the form of an above-average increase in body temperature several hours after injection, restoration of the physiological morning/evening differential of at least 0.5°C, or an increase in mean body temperature during the course of treatment.

In contrast, in the case of tumor fever, attempts should be made to restore a normal core temperature rhythm by using lower strengths.

c) Immunological response

e.g. an increase in leukocytes (in particular in absolute lymphocyte and eosinophil counts); an improvement of the cellular immune status in the recall antigen test or by determining lymphocyte sub-populations.

d) Local inflammatory response

Local inflammatory reaction at the injection site with a maximal diameter of up to 5 cm.

Maintenance phase

Unless otherwise prescribed:

Individual doses can already be obtained with the 0.02 mg formulation. Otherwise, the dose should be increased in increments to 0.2 mg, 2 mg or 20 mg, given in each case as 2 - 3 injections a week.

As excessive responses are known to occur when switching to higher-strength concentrations, it is advisable to initially administer only half an ampoule of the next higher concentration. If the response is already too excessive with the 0.02 mg formulation, patients should be switched to the D6 formulation. If this should also provoke an excessive response, only 1/3 of potency level D 6 should be used. Alternatively, the patient should be switched to the D10 formulation or to abnobaVISCUM obtained from a different host tree. In the above-mentioned cases, the use of 0.5 ml or 0.3 ml abnobaVISCUM with the aid of a scaled 1 ml syringe is recommended.

During radiotherapy, chemotherapy or hormone therapy or after surgery, the individual responsiveness of the patients may change and make a dose adjustment necessary.

With the optimal individual concentration or dose determined in this manner, treatment is continued.

To prevent habituation effects, a rhythmic application in the following forms may be applied:

- alternation between lower concentrations or doses in the form of increasing and possibly also decreasing dosages or
- a new rhythm of the injection intervals.

At intervals of 3 - 6 months, the dosage should be reviewed as regards patient reaction and tumor behavior.

**Frequency of application**

Unless otherwise prescribed: subcutaneous injection 2 - 3 x weekly.

**Posology in cases of impaired renal function**

There is insufficient data for concrete dosage recommendations in cases of impaired renal function. General experience up to this point shows no requirement for a dose adjustment.

**Mode of application**

Subcutaneous injection*:* if possible, into an area near the primary or secondary tumor (metastasis). Otherwise, it is advisable to alternate injection sites between each dose (e.g. abdominal skin, upper arm or thigh). Do not inject into inflamed skin areas or irradiated areas. The strict procedure for subcutaneous injection should be followed.

As a precaution, it is recommended that abnobaVISCUM is not to be drawn up in a syringe with other medicinal products (see also section 6.2 Incompatibilities).

Ampoules must be injected immediately after opening. Opened ampoules must not be saved for a later injection.

**For potency levels D 10, D 20 and D30 only:**

For potency levels D 10, D 20 and D 30, the required dosage may, in special cases, be mixed with a solution for infusion (physiological saline solution or 5% glucose solution) and administered as a slow i.v. infusion. For 250 ml, the duration of infusion should be at least 90 minutes. Dosage and frequency are based on the patient's current physical constitution and are individually determined by the doctor.

**Duration of use**

The treating physician decides on the duration of use.

In principle, there is no limit to the duration of use, which is decided by the doctor based on the individual risk of relapse and the patient's condition or findings. It should last for several years, usually with intermittent pauses of increasing length.

### 4.3 Contraindications

- known hypersensitivity to mistletoe preparations
- acute inflammatory or highly febrile diseases: treatment should be interrupted until the signs of inflammation subside
- chronic granulomatous diseases and florid autoimmune diseases and those treated with immunosuppressive therapy
- hyperthyroidism with tachycardia

### 4.4 Special warnings and precautions for use

Excessive dose increases (by two orders of magnitude) may cause allergoid reactions requiring emergency treatment. As allergoid reactions are dose-dependent, the therapy can be continued with a reduced dose after the symptoms have subsided.

After each therapeutic pause lasting longer than 4 weeks, the individual dosage must always be redetermined by starting with the 0.02 mg concentration.

Primary brain and spinal tumors or intracranial metastases with the risk of an increase in intracranial pressure: In this case, the preparations should only be administered according to strict determination of the indication and under close clinical control.

The ampoule should be briefly warmed in the hand as the formation of cold agglutinins after i.v. injection have been described for mistletoe solutions for injection which were not at body temperature.

### 4.5 Interactions with other medicinal products and other forms of interaction

There are no investigations available on interactions with other immune modulating substances (e.g., thymus extracts). When administering relevant preparations at close intervals, careful dosage and monitoring of appropriate immune parameters is recommended.

### 4.6 Pregnancy and lactation

There are no clinical data available on pregnant women exposed to abnobaVISCUM.

Investigational studies conducted on animals with abnobaVISCUM Fraxini do not indicate any direct or indirect harmful effects on pregnancy and embryonic development. There are no investigational studies on animals available regarding the effects on delivery and postnatal development, in particular on hematopoiesis and the immune system of the fetus/infant (see section 5.3). The potential risk to humans in these areas is unknown. Caution is advised when used during pregnancy and lactation.

### 4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and operate machines have been performed. Therefore, it is unknown whether abnobaVISCUM influences the ability to drive or use machines. However, if symptoms such as fever occur in association with the use of abnobaVISCUM, the patient must not actively participate in road traffic or use machines until these symptoms have dissipated.

## 4.8 Undesirable effects

A slight increase in body temperature and local inflammatory reactions at the subcutaneous injection site occur at the beginning of therapy almost regularly and are signs of the patient's responsiveness. Temporary mild swelling of regional lymph nodes is also harmless.

In case of a fever greater than 38°C (possibly with fatigue, shivering, general malaise, headache, temporary dizziness) or in cases of large local reactions in excess of 5 cm in diameter, the following injection should only be administered after such symptoms have subsided; and then, at a reduced concentration or dose.

AbnobaVISCUM-induced fever should not be suppressed by antipyretic medications. Should fever persist for longer than three days, possible infectious processes or tumor fever should be taken into consideration.

Localized or systemic allergic or allergoid reactions may occur (usually in the form of generalized itching, urticaria or exanthema, occasionally also with Quincke's edema, chills, dyspnea and bronchospasms, in isolated cases with shock or erythema exsudativum multiforme) which require discontinuation of the preparation and the introduction of medical treatment.

Activation of existing inflammations and inflammatory manifestations of irritation of superficial veins in the injection area are possible. In this case as well, a temporary therapeutic pause until the inflammatory reaction has subsided is necessary.

The occurrence of chronic granulomatous inflammations (sarcoidosis, erythema nodosum) and autoimmune diseases (dermatomyositis) have been reported during mistletoe therapy.

Symptoms of an increase in intracranial pressure have also been reported during mistletoe therapy of brain tumors/metastases.

**Reporting of suspected undesirable effects**

The reporting of suspected undesirable effects following marketing authorization is of great importance. It enables a continuous monitoring of the risk/benefit relationship of the medicinal product. Members of the health professions are required to report any suspected case of an undesirable effect to the Federal Institute for Drugs and Medical Devices, Dept. Pharmacovigilance, Kurt-Georg-Kiesinger Allee 3, 53175 Bonn, Germany, web site: www.bfarm.de.

## 4.9 Emergency measures, symptoms and antidotes

The emergency treatment of anaphylactic shock is based on the clinical symptoms:

Initial measures

Venous access, supply of crystalloid solutions.

Supply of oxygen (endotracheal intubation if necessary or cricothyrotomy and ventilation)

Medicinal therapy

Volume supply:

Treatment of hypovolemia by the rapid administration of crystalloid solutions (full electrolyte solutions).

Intravenous catecholamines:

1 mg epinephrine is diluted with 0.9% saline solution up to 10 ml; 1 ml/min of this diluted solution (= 100 µg epinephrine) is administered by slow i.v. injection (monitoring of pulse and blood pressure, possibly ECG).

In the case of severe, epinephrine-refractory hypotension, additional norepinephrine: 1 mg norepinephrine is diluted with 0.9% saline solution up to 10 ml; 0.5-1 ml of this diluted solution (= 50-100 µg norepinephrine) is administered by i.v. injection (has to be repeated if necessary).

Glucocorticoids:

In cases of severe bronchospasms as well as delayed, progressive symptoms, a one-time intravenous administration of 500-1000 mg prednisolone.

For the prevention of recurring reactions and the treatment of delayed reactions, administration of glucocorticoids over a 24-hour period, e.g., 3 times 125 mg prednisolone intravenously. In patients with insulin-dependent diabetes mellitus or diabetes mellitus treated with other anti-diabetic therapies, a short-term adjustment of the insulin dose may be necessary.

Histamine antagonists (in addition to the primary therapy with volume supply):

To reduce histamine-mediated vasodilation and bronchoconstriction: H1 and H2 antagonists in combination, with the H1 antagonist being administered first, e.g., 2 mg clemastine followed by 50 mg ranitidine intravenously.

Theophylline:

In addition, if necessary, in cases of severe bronchospastic reactions if these do not respond to epinephrine and glucocorticoids: initially 5 mg/kg body weight.

## 5 Pharmacological properties

### 5.1 Pharmacodynamic properties

Cancerostatic and immune modulating properties are described for abnobaVISCUM extracts in vitro, in animal experiments and in human pharmacology.

### 5.2 Pharmacokinetic properties

Not applicable.

### 5.3 Preclinical safety data

Animal trials on acute toxicity and pharmacological safety conducted with abnobaVISCUM Fraxini 20 mg and abnobaVISCUM Pini 20 mg show a good therapeutic index of the medicinal product. There was no evidence of chronic toxicity.

Animal experiments on immunotoxicity in the mouse, which were conducted representatively with the abnobaVISCUM product containing the most lectins (abnobaVISCUM Fraxini 20 mg), showed no immunotoxicologically relevant impact on general and specific immune parameters or on the humoral and cellular immune response at doses up to four times greater than the daily maximum therapeutic dose. In further animal experiments, there was evidence of a weakening of the resistance to mouse melanoma cells at doses four times greater than the daily maximum dose of the preparation abnobaVISCUM Fraxini 20 mg.

Investigations with abnobaVISCUM Fraxini 20 mg and abnobaVISCUM Pini 20 mg on embryotoxicity yielded no evidence of an embryotoxic risk for abnobaVISCUM Fraxini 20 mg and abnobaVISCUM Pini 20 mg in clinical use.

In in-vitro and in-vivo tests with abnobaVISCUM Fraxini 20 mg and abnobaVISCUM Pini 20 mg, there was no evidence of mutagenicity.

## 6 Pharmaceutical particulars

### 6.1 List of excipients

<u>20 mg strength:</u>

No excipients

<u>2 mg and 0.2 mg strengths:</u>

Sodium monohydrogen phosphate 2 $H_2O$, ascorbic acid, water for injection

0.02 mg strength:
Sodium monohydrogen phosphate 2 $H_2O$, sodium dihydrogen phosphate $H_2O$, ascorbic acid, water for injection

Potency levels D 6, D 10, D 20, D 30:
No excipients

### 6.2 Incompatibilities
See section 4.2 Mode of application

### 6.3 Shelf life
20 mg, 2 mg, 0.2 mg, 0.02 mg strengths: 3 years
Potency levels D 6, D 10, D 20, D 30: 5 years

### 6.4 Special precautions for storage
20 mg, 2 mg, 0.2 mg and 0.02 mg strengths:
Store in a refrigerator (2°C to 8°C). Do not freeze.

Potency levels D 6, D 10, D 20 and D 30:
Do not store above 25°C. Do not freeze. Storage in a refrigerator is recommended.

### 6.5 Nature and contents of container
All abnobaVISCUM® preparations:
Pack with 8 ampoules of 1 ml solution for injection or liquid dilution for injection.
Pack with 48 ampoules of 1 ml solution for injection or liquid dilution for injection.

20 mg to 0.02 mg strengths:
Pack with 21 ampoules of 1 ml solution for injection.

### 6.6 Special precautions for disposal
No special requirements.

## 7 Marketing authorization holder
ABNOBA GmbH, Hohenzollernstr. 16, 75177 Pforzheim, Germany
Telephone: +49 (0) 7231 – 31 64 78, Fax: +49 (0) 7231 – 35 87 14

## 8 Marketing authorization numbers and
## 9 Date of marketing authorization

| Name of the product | Product marketing authorization number | Date of first marketing authorization |
|---|---|---|
| abnobaVISCUM Abietis 20 mg | 4241.00.00 | 15.01.1985 |
| abnobaVISCUM Abietis 2 mg | 4241.01.00 | 15.01.1985 |

| Name of the product | Product marketing authorization number | Date of first marketing authorization |
|---|---|---|
| abnobaVISCUM Abietis 0.2 mg | 4241.02.00 | 15.01.1985 |
| abnobaVISCUM Abietis 0.02 mg | 4241.03.00 | 15.01.1985 |
| abnobaVISCUM Abietis D 6 | 24369.00.00 | 31.01.1992 |
| abnobaVISCUM Abietis D 10 | 24369.01.00 | 31.01.1992 |
| abnobaVISCUM Abietis D 20 | 24369.02.00 | 31.01.1992 |
| abnobaVISCUM Abietis D 30 | 24369.03.00 | 31.01.1992 |
| abnobaVISCUM Aceris 20 mg | 11435.00.00 | 30.01.1992 |
| abnobaVISCUM Aceris 2 mg | 11435.01.00 | 30.01.1992 |
| abnobaVISCUM Aceris 0.2 mg | 11435.02.00 | 30.01.1992 |
| abnobaVISCUM Aceris 0.02 mg | 11435.03.00 | 30.01.1992 |
| abnobaVISCUM Aceris D 6 | 11435.00.01 | 04.02.1992 |
| abnobaVISCUM Aceris D 10 | 11435.01.01 | 04.02.1992 |
| abnobaVISCUM Aceris D 20 | 11435.02.01 | 04.02.1992 |
| abnobaVISCUM Aceris D 30 | 11435.03.01 | 04.02.1992 |
| abnobaVISCUM Amygdali 20 mg | 11439.00.00 | 29.01.1992 |
| abnobaVISCUM Amygdali 2 mg | 11439.01.00 | 29.01.1992 |
| abnobaVISCUM Amygdali 0.2 mg | 11439.02.00 | 29.01.1992 |
| abnobaVISCUM Amygdali 0.02 mg | 11439.03.00 | 29.01.1992 |
| abnobaVISCUM Amygdali D 6 | 11439.00.01 | 05.02.1992 |
| abnobaVISCUM Amygdali D 10 | 11439.01.01 | 05.02.1992 |
| abnobaVISCUM Amygdali D 20 | 11439.02.01 | 05.02.1992 |
| abnobaVISCUM Amygdali D 30 | 11439.03.01 | 05.02.1992 |
| abnobaVISCUM Betulae 20 mg | 11443.00.00 | 30.01.1992 |
| abnobaVISCUM Betulae 2 mg | 11443.01.00 | 30.01.1992 |
| abnobaVISCUM Betulae 0.2 mg | 11443.02.00 | 30.01.1992 |
| abnobaVISCUM Betulae 0.02 mg | 11443.03.00 | 30.01.1992 |
| abnobaVISCUM Betulae D 6 | 11443.00.01 | 31.01.1992 |
| abnobaVISCUM Betulae D 10 | 11443.01.01 | 31.01.1992 |
| abnobaVISCUM Betulae D 20 | 11443.02.01 | 31.01.1992 |
| abnobaVISCUM Betulae D 30 | 11443.03.01 | 31.01.1992 |
| abnobaVISCUM Crataegi 20 mg | 11447.00.00 | 29.01.1992 |
| abnobaVISCUM Crataegi 2 mg | 11447.01.00 | 29.01.1992 |
| abnobaVISCUM Crataegi 0.2 mg | 11447.02.00 | 29.01.1992 |
| abnobaVISCUM Crataegi 0.02 mg | 11447.03.00 | 29.01.1992 |
| abnobaVISCUM Crataegi D 6 | 11447.00.01 | 31.01.1992 |
| abnobaVISCUM Crataegi D 10 | 11447.01.01 | 31.01.1992 |
| abnobaVISCUM Crataegi D 20 | 11447.02.01 | 31.01.1992 |
| abnobaVISCUM Crataegi D 30 | 11447.03.01 | 31.01.1992 |
| abnobaVISCUM Fraxini 20 mg | 11451.00.00 | 24.01.1992 |
| abnobaVISCUM Fraxini 2 mg | 11451.01.00 | 24.01.1992 |
| abnobaVISCUM Fraxini 0.2 mg | 11451.02.00 | 24.01.1992 |
| abnobaVISCUM Fraxini 0.02 mg | 11451.03.00 | 24.01.1992 |
| abnobaVISCUM Fraxini D 6 | 11451.00.01 | 06.02.1992 |
| abnobaVISCUM Fraxini D 10 | 11451.01.01 | 06.02.1992 |
| abnobaVISCUM Fraxini D 20 | 11451.02.01 | 06.02.1992 |
| abnobaVISCUM Fraxini D 30 | 11451.03.01 | 06.02.1992 |
| abnobaVISCUM Mali 20 mg | 11455.00.00 | 30.01.1992 |
| abnobaVISCUM Mali 2 mg | 11455.01.00 | 30.01.1992 |
| abnobaVISCUM Mali 0.2 mg | 11455.02.00 | 30.01.1992 |
| abnobaVISCUM Mali 0.02 mg | 11455.03.00 | 30.01.1992 |

| Name of the product | Product marketing authorization number | Date of first marketing authorization |
|---|---|---|
| abnobaVISCUM Mali D 6 | 11455.00.01 | 31.01.1992 |
| abnobaVISCUM Mali D 10 | 11455.01.01 | 31.01.1992 |
| abnobaVISCUM Mali D 20 | 11455.02.01 | 31.01.1992 |
| abnobaVISCUM Mali D 30 | 11455.03.01 | 31.01.1992 |
| abnobaVISCUM Pini 20 mg | 11459.00.00 | 29.01.1992 |
| abnobaVISCUM Pini 2 mg | 11459.01.00 | 29.01.1992 |
| abnobaVISCUM Pini 0.2 mg | 11459.02.00 | 29.01.1992 |
| abnobaVISCUM Pini 0.02 mg | 11459.03.00 | 29.01.1992 |
| abnobaVISCUM Pini D 6 | 11459.00.01 | 31.01.1992 |
| abnobaVISCUM Pini D 10 | 11459.01.01 | 31.01.1992 |
| abnobaVISCUM Pini D 20 | 11459.02.01 | 31.01.1992 |
| abnobaVISCUM Pini D 30 | 11459.03.01 | 31.01.1992 |
| abnobaVISCUM Quercus 20 mg | 11463.00.00 | 29.01.1992 |
| abnobaVISCUM Quercus 2 mg | 11463.01.00 | 29.01.1992 |
| abnobaVISCUM Quercus 0.2 mg | 11463.02.00 | 29.01.1992 |
| abnobaVISCUM Quercus 0.02 mg | 11463.03.00 | 29.01.1992 |
| abnobaVISCUM Quercus D 6 | 11463.00.01 | 31.01.1992 |
| abnobaVISCUM Quercus D 10 | 11463.01.01 | 31.01.1992 |
| abnobaVISCUM Quercus D 20 | 11463.02.01 | 31.01.1992 |
| abnobaVISCUM Quercus D 30 | 11463.03.01 | 31.01.1992 |

## 10 Date of revision of the text

July 2015

## 11 General classification for supply

Pharmacy-only medicine