

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 Active substance:
abnobaVISCUM Abietis D 6/D 10/D 20/D 30	Viscum album Abietis ex herba recente col. Dil. 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 (plant to extract = 1:50) 1 ml/0.1 ml/0.01 ml/0.001 ml Extractant: Disodium phosphate dihydrate, 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. 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 (plant to extract = 1:50) 1 ml/0.1 ml/0.01 ml/0.001 ml Extractant: Disodium phosphate dihydrate, 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. 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 (plant to extract = 1:50) 1 ml/0.1 ml/0.01 ml/0.001 ml Extractant: Disodium phosphate dihydrate, 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. 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 (plant to extract = 1:50) 1 ml/0.1 ml/0.01 ml/0.001 ml Extractant: Disodium phosphate dihydrate, 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. 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 (plant to extract = 1:50) 1 ml/0.1 ml/0.01 ml/0.001 ml Extractant: Disodium phosphate dihydrate, 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. 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 (plant to extract = 1:50) 1 ml/0.1 ml/0.01 ml/0.001 ml Extractant: Disodium phosphate dihydrate, 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: Disodium phosphate dihydrate, 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: Disodium phosphate dihydrate, 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: Disodium phosphate dihydrate, 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.

AbnobaVISCUM contains less than 1 mmol sodium (23 mg) per 1 ml, that is to say essentially "sodium-free".

4.5 Interactions with other medicinal products and other forms of interaction

AbnobaVISCUM Fraxini 20 mg, abnobaVISCUM Abietis 20 mg and abnobaVISCUM Pini 20 mg were tested for their potential to inhibit various CYP450 isoenzymes in the concentrations 0.2, 2.0 and 200 µg/ml and to induce them in the concentrations 0.2, 2.0 and 4 µg/ml. No clear induction and no or only a marginal inhibition of the tested concentrations could be observed. The data indicate that no interactions with other medicinal products are to be expected.

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 Fertility, pregnancy and lactation

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

Preclinical embryotoxicity studies conducted in rats with abnobaVISCUM Fraxini 20 mg do not indicate any special risks to humans. 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 Overdose / overreaction: Symptoms, emergency measures and antidotes

Occurrence of anaphylactic reactions

Initial symptoms of an anaphylactic reaction include itching or a burning sensation of the palms or soles, the tongue and palate as well as itching, erythema and urticaria of the skin and mucous membranes. During the further course of the reaction nausea, spasms, vomiting, rhinorrhea, hoarseness, dyspnea, tachycardia and hypotension, but also shock and circulatory collapse can occur.

The emergency treatment of the anaphylactic reaction is performed in accordance with the current guidelines.

Adequate emergency equipment has to be available.

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

The acute toxicity of abnobaVISCUM Fraxini 20 mg and abnobaVISCUM Pini 20 mg was investigated in male and female rats and mice following subcutaneous and intravenous application.

In a 28-Day dose-range-finding study on subacute toxicity 3 doses were tested in male and female rats: 0.2, 0.66 and 2 ml per kg rat body weight of abnobaVISCUM Fraxini 20 mg were administered daily by subcutaneous injection from day 1 to 5 and changed to thrice weekly from day 6 onwards. The derived maximum tolerated dose (MTD) is 2 ml/kg body weight/day when administered thrice weekly.

In a 90-Day subchronic toxicity study a NOAEL of 2 ml/kg body weight/day was determined by administration of 3 different doses (0.2, 0.66 and 2 ml abnobaVISCUM Fraxini 20 mg/kg/day injected subcutaneously thrice weekly) in male and female rats.

Investigations on chronic toxicity were not conducted.

Animal safety pharmacology studies (mouse, rat, dog) with subcutaneously injected abnobaVISCUM Fraxini 20 mg revealed no special safety risks for humans.

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.

Embryotoxicity studies with 3 different doses (subcutaneous injections of 0.25, 0.75 and 2.25 ml of abnobaVISCUM Fraxini 20 mg per kg rat body weight/day over 12 consecutive days from day 6 to day 17 of pregnancy (organogenesis)) were performed in pregnant rats. The systemic no-observed-effect level (NOEL) was 0.25 ml/kg rat body weight/day abnobaVISCUM Fraxini 20 mg without signs of embryotoxicity in the rat dams. Based on these rat embryotoxicity studies the preclinical data do not indicate a special risk for humans.

In two in-vitro experiments with abnobaVISCUM Fraxini 20 mg, the Ames test (Salmonella typhimurium) and the chromosome aberration test (human lymphocytes), as well as in the in-vivo micronucleus test (murine bone marrow cells) there was no evidence for mutagenicity or cytogenetic damages such as clastogenicity/chromosome breakages, or micronuclei.

6 Pharmaceutical particulars

6.1 List of excipients

20 mg strength:

No excipients

2 mg and 0.2 mg strengths:

Disodium phosphate dihydrate, ascorbic acid, water for injection

0.02 mg strength:

Disodium phosphate dihydrate, sodium dihydrogen phosphate monohydrate, 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, Allmendstrasse 55, 75223 Niefern-Öschelbronn, Germany

Telephone: +49 (0) 7233 7043 200, Telefax: +49 (0) 7233 7043 301

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
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

Name of the product	Product marketing authorization number	Date of first marketing authorization
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
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

February 2021

11 General classification for supply

Pharmacy-only medicine