

Package leaflet: Information for the user

abnobaVISCUM [host tree] [strength or potency level]

Solution for injection (for the 20 mg, 2 mg, 0.2 mg, 0.02 mg strengths)

Liquid dilution for injection (for potency levels D 6, D 10, D 20, D 30)

Distinguished according to the type of mistletoe host tree:

Abietis (fir),
Aceris (maple),
Amygdali (almond tree),
Betulae (birch),
Crataegi (hawthorn),
Fraxini (ash),
Mali (apple tree),
Pini (pine),
Quercus (oak).

Active substance:

20 mg, 2 mg, 0.2 mg, 0.02 mg strengths:

Each ampoule contains 1 ml / 0.1 ml / 0.01 ml / 0.001 ml extract of fresh mistletoe herb from the respective host tree.

Potency levels D 6, D 10, D 20, D 30:

Each ampoule contains 1 ml Viscum album [host tree] ex herba recente col. D 6 / D 10 / D 20 / D 30

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please contact your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others.

Please note! The dosage strength of 20 mg may only be applied when previously the strengths 2 mg and 0.2 mg were well tolerated.

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1. WHAT abnobaVISCUM IS AND WHAT IT IS USED FOR

abnobaVISCUM is an anthroposophical medicine for extended treatment in tumor diseases.

Therapeutic indications:

abnobaVISCUM is used according to the anthroposophical understanding of man and nature to stimulate the forming and integrative forces for the elimination and re-assimilation of growth processes which have become independent in adults, e.g.:

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

2. BEFORE YOU USE abnobaVISCUM

Do not use abnobaVISCUM:

- in cases of known hypersensitivity to mistletoe preparations.
- in cases of acute inflammatory or highly febrile diseases (body temperature above 38°C), you should not start or continue treatment until all symptoms of fever or inflammation have subsided.
- in cases of chronic granulomatous diseases, autoimmune diseases with very pronounced symptoms of disease and those treated with immunosuppressive therapy.
- in cases of hyperthyroidism with rapid heartbeat.

Particular caution should be exercised with abnobaVISCUM:

- when increasing the dose: Excessive dose increases (by two orders of magnitude) may cause allergic reactions (similar to allergic hypersensitivity reactions) requiring emergency treatment.

- after therapeutic pauses, your responsiveness to the administration of mistletoe may have changed. Your doctor will decide whether and to what extent you should receive a lower initial dose.
- in the case of primary brain and spinal tumors or brain metastases with the risk of an increase in intracranial pressure, abnobaVISCUM should only be used with express medical prescription.
- before injection, you should warm the ampoule briefly in your hand.

Pregnancy and breastfeeding:

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

Experimental embryotoxicity studies conducted on rats with abnobaVISCUM Fraxini 20 mg do not indicate any particular risk for humans. Neither are there adequate animal studies available on the effects on delivery and postnatal development, particularly on the development of blood formation and the immune system in the unborn and infants. The potential risk to humans in these areas is unknown. Caution is advised when used during pregnancy and breastfeeding. Like all medicines, abnobaVISCUM should only be used during pregnancy and breastfeeding after consulting your doctor.

Interactions with other medicines:

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. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, even if they do not require a prescription.

Ability to drive and use machines:

It is unknown whether abnobaVISCUM influences the ability to drive or use machines. If you experience symptoms such as fever in association with the use of abnobaVISCUM (see possible side effects), you must not actively participate in road traffic or use machines until these symptoms have dissipated.

abnobaVISCUM contains sodium:

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

3. HOW TO USE abnobaVISCUM

Mode of application:

The subcutaneous injection should take place, if possible, into an area near the primary or secondary tumor (metastasis). Otherwise, it is advisable to alternate injection sites between each dose (different abdominal areas, if necessary thigh or upper arm). 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 medicines.

After cleaning the injection site (for example by wiping with 70% alcohol), make a fold in the skin and insert the syringe needle diagonally. Pull the syringe plunger slightly back. If blood appears, a blood vessel has been hit. In this case, you must repeat the injection at another site. If no blood appears, inject slowly, then pull the needle out and press a pad briefly onto the injection site.

In any case, it is recommended that the injection technique is taught by an experienced person.

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 D 30 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 your current physical constitution and are individually determined by your doctor.

Dosage and frequency of use:

Initiation phase:

Unless otherwise prescribed, the usual dosage is 1 ml solution for injection of the given strength or potency level. You should start the treatment with the 0.02 mg strength three times weekly (for the strengths 0.02 mg, 0.2 mg, 2 mg, 20 mg and potency level D 6) and then continue carefully with the next higher doses, increasing gradually until you have reached the optimal dose. The dosage is always determined individually according to the instructions of your doctor and is based on your body's response.

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

a) A change in your subjective state of well-being: 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 you that dosing is within the therapeutically effective range.

On the day of injection, possible fatigue, shivering, general malaise, headache and transient dizziness are not signs of intolerance; moreover, these signs indicate 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.

b) Temperature response: a one-off temperature increase within a few hours of injection, restoration of the physiological morning/evening differential of at least 0.5°C, or a rise 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 concentrations.

c) Immunological response: Your doctor can detect a positive response of your immune system by laboratory tests of your blood. This may, for example, be shown by an increase in the number of certain white blood cells (lymphocytes and eosinophils) in the blood and by improvement of the cellular immune status in the recall antigen test or in the determination of lymphocyte subpopulations.

d) Local inflammatory response: A local reaction occurs at the injection site. Such reactions should not exceed 5 cm in diameter.

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, you should be switched to the D 6 formulation. If this should also provoke an excessive response, only 1/3 of an ampoule should be used. Alternatively, you should be switched to the D 10 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, your individual responsiveness may change and thus 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 form is recommended:

- 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.

Dosage 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.

Duration of use:

In principle, there is no limit to the duration of use, which is decided by your doctor based on the individual risk of tumor relapse (re-appearance of a similar tumor following previous treatment) and on your individual condition or findings. It should last for several years, usually with intermittent pauses of increasing length.

Application errors:

If you have used a greater quantity of abnobaVISCUM than you should, reactions like those described under side effects may occur. The next injection should not be taken then until after these symptoms have subsided, and in a reduced dose.

If you have forgotten a dose of abnobaVISCUM, follow your normal therapy plan for the additional injections.

If you stop using abnobaVISCUM, you must start again with the lower initial dosage when you restart the therapy.

4. POSSIBLE SIDE EFFECTS

Like all medicines, abnobaVISCUM can cause side effects, although not everybody gets them. 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 response. 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 skin 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 fever-reducing medications. Should fever persist for longer than three days, possible infectious processes or tumor fever should be taken into consideration. Local or general allergic or allergy-like reactions may occur, usually in the form of generalized itching, hives, skin rashes, occasionally also with allergic swelling in the mouth and throat (Quincke's edema), chills, shortness of breath and spasms of the respiratory tract, in isolated cases with shock or an acute inflammatory disease of the skin or mucous membranes (erythema exsudativum multiforme) which require you to stop abnobaVISCUM and require immediate medical treatment.

Activation of existing inflammations and inflammatory irritations 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 side effects:

If you get any side effects, talk to your doctor or pharmacist or your medical specialist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the Federal Institute for Drugs and Medical Devices, Dept. Pharmacovigilance, Kurt-Georg-Kiesinger Allee 3, 53175 Bonn, Germany, web site: www.bfarm.de. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE abnobaVISCUM

20 mg, 2 mg, 0.2 mg, 0.02 mg strengths:

Store in a refrigerator (2°C to 8°C). Do not freeze.

Potency levels D 6, D 10, D 20, D 30:

Do not store above 25°C. Do not freeze. Storage in a refrigerator is recommended.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the ampoules and on the carton.

6. OTHER INFORMATION

What abnobaVISCUM contains:

20 mg, 2 mg, 0.2 mg, 0.02 mg strengths:

The active substance is 1 ml / 0.1 ml / 0.01 ml / 0.001 ml extract of fresh mistletoe herb from the respective host tree (plant to extract = 1:50).

Extractant: Disodium phosphate dihydrate, ascorbic acid, water for injection (2.03 : 0.34 : 97.63)

Potency levels D 6, D 10, D 20, D 30:

The active substance is 1 ml Viscum album [host tree] ex herba recente col. Dil. D 6 / D 10 / D 20 / D 30 (GHP [German Homeopathic Pharmacopoeia], V. 32)

Other ingredients:

20 mg strength: None

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: None

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 20 mg contains an extract of 20 mg fresh mistletoe herb in one ampoule.

What abnobaVISCUM looks like and contents of the pack:

20 mg, 2 mg, 0.2 mg, 0.02 mg strengths:

abnobaVISCUM is available in packs of 8, 21 and 48 ampoules, each containing 1 ml of solution for injection. The medicine has a greenish-yellow to yellow color [20 mg]. / The medicine has a light greenish-yellow to yellow color [2 mg]. / The medicine is colorless [0.2 mg and 0.02 mg]. Flocculation can occur in all aqueous plant extracts during storage. This has no significance for the effectiveness

Potency levels D 6, D 10, D 20, D 30:

abnobaVISCUM is available in packs of 8 and 48 ampoules, each containing 1 ml of liquid dilution for injection. The medicine is colorless to light brown colored [D 6]. / The medicine is colorless [D 10, D 20 and D 30].

Marketing Authorization Holder and Manufacturer:

ABNOBA GmbH

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