

# Summary of treatment protocols Bladder cancer

## Summary of treatment protocols for bladder cancer

For detailed information, please refer to the Summary of Product Characteristics.

## Precautionary measures before starting treatment

Contraindications:	<ul> <li>Known hypersensitivity to mistletoe preparations</li> <li>Acute inflammatory disorders or disorders accompanied by high fever: treatment should be discontinued until all symptoms of inflammation have subsided.</li> <li>Chronic granulomatous diseases, florid autoimmune diseases and those treated with immuno-suppressive therapy</li> <li>Hyperthyroidism with tachycardia</li> </ul>
Surgery:	In pre-operative patients, injections can be administered up to the day before surgery. Post-operatively, therapy should not be started until wound healing is complete.
Chemotherapy / Immunotherapy:	Therapy should be started as soon as possible before chemotherapy or immunotherapy. It is also possible to start mistletoe therapy during chemotherapy or immunotherapy, but injections should not be administered on the day of the chemotherapy or immunotherapy.

## Side effects at the start of therapy

Each of the reactions 1 to 4 indicates an optimal dosage:

- 1 A local inflammatory reaction at the injection site with a diameter of 5 cm or less.
- 2 A temporary temperature increase of 0.5°C to 1.0°C within 12 hours of the injection.

The intensity of reactions 1 and 2 diminishes after approximately 2  $\frac{1}{2}$  weeks of treatment (if this is not the case, treatment should be continued at a strength of 0.02 mg for a further 2  $\frac{1}{2}$  weeks before increasing to the next higher dose).

- 3 Change in subjective state of health: alleviation of pain, deeper sleep, improved appetite.
- 4 Fatigue, slight chills, general malaise, headache and transient dizziness that occur on the day of injection and subside within 24 hours also indicate that the correct dose has been administered.

## **Excessive side effects**

The dose is too high, if:

- the local inflammatory reaction is greater than 5 cm, but less than 10 cm in diameter. In this case, the dose should be reduced to 0.5 ml (half an ampoule) for the next three injections.
- the local inflammatory reaction is greater than 10 cm in diameter: in this case, the next lower strength is injected for 2 ½ weeks (8 ampoules).
- there is persistent weakness, nausea and/or dizziness: in this case, the next lower strength is injected for 2 ½ weeks.
- the injections **continue to provoke excessively severe reactions and side effects:** in this case, abnobaVISCUM from the same type of mistletoe host tree with potency level D6 (0.002 mg) should be administered subcutaneously (SC) three times a week (8 ampoules in total). Therapy should then be started according to the protocol.

## Summary of treatment protocols

Bladder cancer associated with a good general condition before, during or after standard therapy such as chemotherapy or immunotherapy.

Type: abnobaVISCUM Quercus

**WEEKS 1 to 3:** 0.02 mg strength, 1 ml (= 1 ampoule) SC three times weekly (8 ampoules in total = one pack of 8) **WEEKS 3 to 6:** 0.2 mg strength, 1 ml (= 1 ampoule) SC three times weekly (8 ampoules in total = one pack of 8)

WEEK 7 and subsequent weeks: 2 mg strength, 1 ml (= 1 ampoule) SC three times weekly

For maintenance therapy, see below.

Bladder cancer associated with a poor general condition before, during or after standard therapy such as chemotherapy or immunotherapy.

Type: abnobaVISCUM Quercus

WEEKS 1 to 5: 0.02 mg strength, 1 ml (= 1 ampoule) SC three times weekly (16 ampoules in total = two packs of 8) WEEKS 5 to 7: 0.2 mg strength, 1 ml (= 1 ampoule) SC three times weekly (8 ampoules in total = one pack of 8) WEEK 6 and subsequent weeks: 2 mg strength, 1 ml (= 1 ampoule) SC three times weekly

For maintenance therapy, see below.

# ABNOBAVISCUM

# Summary of treatment protocols **Bladder cancer**

Metastatic bladder cancer before, during or after standard therapy such as chemotherapy or immunotherapy. Type: abnobaVISCUM Fraxini

WEEKS 1 to 3: 0.02 mg strength, 1 ml (= 1 ampoule) SC three times weekly (8 ampoules in total = one pack of 8) WEEKS 3 to 6: 0.2 mg strength, 1 ml (= 1 ampoule) SC three times weekly (8 ampoules in total = one pack of 8) WEEK 6 and subsequent weeks: 2 mg strength, 1 ml (= 1 ampoule) SC three times weekly

For maintenance therapy, see below.

## Palliative therapy for bladder cancer

Type: abnobaVISCUM Quercus

WEEKS 1 to 5: 0.02 mg strength, 1 ml (= 1 ampoule) SC three times weekly (16 ampoules in total = two packs of 8) WEEKS 5 to 7: 0.2 mg strength, 1 ml (= 1 ampoule) SC three times weekly (8 ampoules in total = one pack of 8) WEEK 7 and subsequent weeks: 2 mg strength, 1 ml (= 1 ampoule) SC three times weekly

For maintenance therapy, see below.

## Maintenance therapy

After the highest strength specified above has been reached, treatment is continued at this strength for a period of two years. After this, injections are administered twice weekly for a period of one year. After three years, therapeutic pauses of three months can be introduced.

CAUTION: After therapeutic pauses of more than four weeks, treatment must, as at the beginning of therapy, be started again at a low dose (0.02 mg).

<b>Treatment information</b> You can reach us by phone betwe numbers: +49 (0)7233 70 43 200 or free call 0800 22 66 222 Alternatively, you can reach us by e-r	en 08:00 and 16:30 at the following telephone nail at info@abnoba.de		
Please note that patients with superficial bladder cancer may be eligible for in- clusion in the TIM (therapeutic installation of a mistletoe extract) study. We would be happy to provide you with the names of the study centres.			
abnobaVISCUM® is available in 1 D6 (0.002 mg), 0.02 mg, 0.2 mg, 2 and the following pack sizes 8 ampoules (start of therapy) 21 ampoules (quarterly pack) 48 ampoules (for hospital use)	•••		
Full name, for example: abnobaVISCUM Quercus 0.02 mg, 8 ampoules			