Report on i.v. administration of abnobaVISCUM

Warning: off-label use

The following intravenous infusion therapy with abnobaVISCUM® is not an authorised form of treatment and constitutes off-label use.

Indication

Infusions are mainly used in the treatment of painful conditions due to cancer and are usually administered once weekly in the event of tumour progression.

Dosage and frequency of administration

- In the first 2 weeks, one ampoule (1 ml) of abnobaVISCUM is given at the last subcutaneously administered strength. Thereafter, as shown in the following table, the dose is increased to the next highest strength.
- If the patient is undergoing mistletoe therapy for the first time, one ampoule of abnobaVISCUM at a strength of 0.02 mg is infused.

Assuming good systemic tolerability, one ampoule of the next highest strength is infused every other week, until the 20 mg strength has been reached. In the 3 subsequent infusions, the dose is increased to 2, 4 and 6 ampoules of the 20 mg strength. As a rule, 16 infusions are given.

TREATMENT REGIMEN in patients who have not previously undergone mistletoe therapy.

Week	1	2	3	4	5	6	7	8
Strength of abnobaVISCUM								
0,02 mg	•	•						
0,2 mg			•	•				
2 mg					•	•		
20 mg							•	•
If well tolerated, the strength is increased								
Week	9	10	11	12	13	14	15	16
Strength of abnobaVISCUM								
40 mg	•	•						
80 mg			•	•				
120 mg					•	•	•	•

Method of administration

AbnobaVISCUM is administered at the respective dose as an intravenous infusion in 250 ml sterile normal sodium chloride solution. The duration of infusion should be at least 120 minutes. If symptoms of an allergic or allergoid reaction occur during infusion, the infusion must be discontinued immediately.
If necessary, emergency medical procedures should be performed, as described below in the section "Emergency measures, symptoms and antidotes".

Side effects

A slight rise in body temperature can occur at the beginning of therapy. Transient mild swelling of individual lymph nodes is also harmless.
If fever exceeds 38 °C (possibly accompanied by fatigue, chills, general malaise, headache and transient dizziness), the next infusion should not be administered until these symptoms have resolved and it should be given at a reduced concentration or dose.

The fever precipitated by abnobaVISCUM infusions should not be suppressed with antipyretic medicines. If fever persists for longer than 3 days, an infectious process or tumour fever should be considered.
Localised or systemic allergic or allergoid reactions can occur (usually in the form of generalised pruritus, urticaria or exanthema, sometimes with Quincke's oedema, chills, dyspnoea and bronchospasm, in isolated cases with shock or as erythema multiforme), in which case the infusion must be stopped immediately and medical therapy initiated.
Activation of pre-existing inflammation or inflammatory irritation of superficial veins in the infusion area is possible. In such cases, a temporary treatment break is also required, until the inflammatory reaction has subsided.
The occurrence of chronic granulomatous inflammation (sarcoidosis, erythema nodosum) and autoimmune disorders (dermatomyositis) has been reported during mistletoe therapy.
Symptoms of increased intracerebral pressure in brain tumours/brain metastases have also been reported during mistletoe therapy.
An immunosuppressive effect of higher doses cannot be excluded. No systematic investigations are available.

Emergency measures, symptoms and antidotes

Emergency therapy of anaphylactic shock is guided by clinical symptoms:
Initial measures
Establish venous access, administration of crystalloid solutions.
Oxygen administration (if required, endotracheal intubation or coniotomy and ventilation)
Drug therapy
Volume replacement therapy:
Treatment of hypovolaemia with rapid administration of crystalloid solutions (physiological electrolyte solutions).
Catecholamines i.v.:
1 mg adrenaline is diluted to 10 ml with 0.9% sodium chloride solution; 1 ml/min of this diluted solution (= 100 µg adrenaline) is slowly injected i.v. (check pulse and blood pressure, ECG if required).
In the event of adrenaline-resistant, severe hypotension, additional administration of noradrenaline: 1 mg noradrenaline is diluted to 10 ml with 0.9% sodium chloride solution; 0.5–1 ml of this diluted solution (= 50–100 µg noradrenaline) is injected i.v. (repeat as required).
Glucocorticoids:
In cases of severe bronchospasm or delayed progressive symptoms, a single dose of 500–1000 mg prednisolone i.v. should be administered.
For the prevention of recurrent reactions and therapy of delayed reactions, glucocorticoid administration over 24 h, e.g. three doses of 125 mg prednisolone i.v. In patients with insulin-dependent diabetes mellitus or diabetes requiring other antidiabetic treatments, a temporary adjustment of the insulin dose may be necessary.
Histamine antagonists (in addition to primary therapy with volume replacement):
To reduce histamine-mediated vasodilatation and bronchoconstriction: H1 and H2 antagonists in combination, whereby the H1 antagonist is administered first, e.g. 2 mg clemastine followed by 50 mg ranitidine i.v.
Theophylline:
If necessary, as additional treatment of severe bronchospastic reactions, if these have not responded to adrenaline and glucocorticoids: initially 5 mg/kg body weight.

Contraindications and warnings

Please also heed the contraindications and warnings as described for subcutaneous administration. (See recommendations for use)

Therapy advice

If you have any questions regarding intravenous administration of abnobaVISCUM®, please do not hesitate to contact our therapy advice service (e-mail: info@abnoba.de / Tel.: 0800 22 66 222) at any time.