



Use of **ISCADOR®**

A manual for patients



Practical use of **ISCADOR**

ISCADOR is administered by subcutaneous injections under the skin – like an insulin injection and it is easy to learn how to apply the injection. However, please note that you should carry out at least the first injection together with your physician. He can show you where to place the injection and what you have to do. Always carefully follow your physician's instructions. Generally, ISCADOR is injected two to three times per week. The best time to apply the injection is in the morning.

What should you keep in mind for the injection?

ISCADOR ampoules must be stored in the refrigerator. It is recommended to briefly warm the ampoules in the hand before use.

Suitable injection sites are:

- Abdominal wall
- Lateral thigh (front)

Local inflammatory reactions like reddening around the injection site (with a maximum diameter of up to 5 cm/2 inches) can temporarily develop and are no reason for concern, but rather indicates that there is a positive reaction to the administration of ISCADOR. This local reaction usually subsides in one or two days.

Change injection sites on a regular basis to avoid stronger skin reactions and ensure not to inject into areas of inflamed skin or irradiated areas.

Injection method

The following utensils are required for each injection:

- One ISCADOR ampoule
- A small syringe (2 ml)
- A short, thin needle (e.g. $0.4 \times 19 \text{ mm}/3/4$ ", No. 20)
- An alcohol swab
- Possibly a small plaster



Preparation

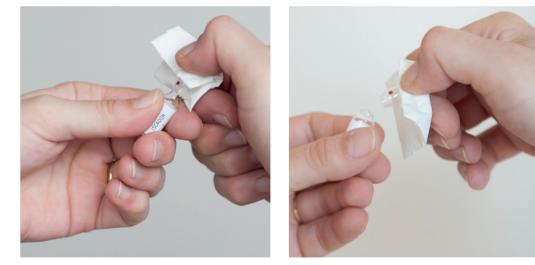
Get the necessary utensils ready.

Put the needle (cannula) with the cap on the syringe and firmly press it onto the syringe.

1. Open the ampoule



Remove the liquid in the ampoule head by tapping lightly.

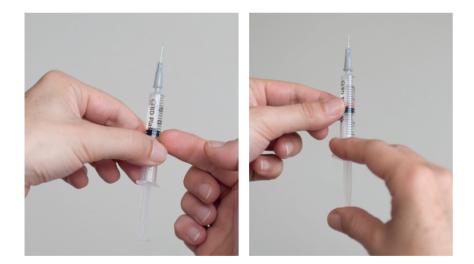


Open the ampoule by breaking the neck under the coloured spot using a swab. For this purpose hold the coloured spot upward and bend the ampoule with light pressure backwards.

2. Drawing the injection liquid



Remove the needle cap and draw the content of the ampoule through the needle into the syringe.



Now, all you need to do is remove the excess air from the syringe. To do so, hold the syringe vertically with the needle pointing upward. Air bubbles on the side or the bottom of the syringe can be moved up by tapping lightly on the syringe (left image). The air can then be removed by slowly pushing the piston (right image). 3. Subcutaneous injection (under the skin)



Your physician will tell you what site is best to apply the injection.

- Disinfect the injection site with an alcohol swab.
- Take a skin fold between two fingers of one hand.
- Rapidly insert the needle into the skin at a 45 degree angle.
- Release the skin fold a bit and inject the content of the ampoule slowly and evenly.
- After the syringe is empty, place the alcohol swab on the injection site and pull the needle out of the skin.
- Press the swab for a few seconds on the injection site. If necessary, you can cover the injection site with a small plaster.

Reactions

General reactions

Especially at the beginning of the therapy the body temperature may increase more than usual and a local inflammatory reaction may develop at the injection site after the injection of ISCADOR. This local inflammatory reaction can largely vary in terms of size or may not develop at all.

Local inflammatory reaction



A mild local inflammation may develop around the injection site. This appears as distinct reddening of the skin with blurred edges. Itching may develop at the same time.

Distinct skin reddening directly after the injection.



The edge of the local reaction becomes smoother after approx. 4 hours. It may itch again.

Typical picture of a local reaction 4 hours after injection.



10 hours after the injection the edge of the local reaction has become flatter and slowly disappears. The reddened area may expand further.

Injection check list

- Please follow the sequence of injections (ampoule number in the box).
- Briefly warm the ampoules in the hand before use.
- Make sure that no air bubbles are left in the syringe before the injection.
- Disinfect the injection site with an alcohol swab.
- Take a skin fold between two fingers of one hand.
- Rapidly insert the needle into the skin at a 45 degree angle.
- Release the skin fold a bit and inject the content of the syringe slowly and evenly.
- After the syringe is empty, place the alcohol swab on the injection site and pull the needle out of the skin.
- Press the swab for a few seconds on the injection site. If necessary, you can cover the injection site with a small plaster.
- Put the protective cap back on the needle to prevent injury and discard the used syringe in the waste.
- Please note the patient information leaflet which comes with all ISCADOR ampoules. The patient information leaflet can also be found online: http://www.pharmnet-bund.de
- Please contact your physician, if you have any further questions and require additional information.

Typical picture of a local reaction 10 hours after injection

Imprint/contact

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Drug information

ISCADOR solution for injections

Based on the product information submitted to the German Health Authorities.

Active ingredient: fermented, aqueous mistletoe extract.

Composition: fermented, aqueous extract from *Viscum album* from various host trees. Other ingredients: sodium chloride and water for injection.

Indications: according to the anthroposophic knowledge of human being and nature. This include in adults: Stimulation of the forming and integration forces for the purpose of elimination and reassimilation of growth processes which have become independent, for example in malignant tumours, also with accompanying impairment of haematopoietic organs; in benign tumours; in defined precancerous disorders; for prevention of tumour recurrence after surgery.

Contraindications: Known allergy to preparations of European mistletoe (*Viscum album* L.). Disorders accompanied by acute inflammation or high fever. Chronic granulomatous diseases, florid autoimmune diseases and those under immunosuppressive therapy. Hyperthyroidsm with tachycardia.

Side effects: a slight increase in body temperature, locally restricted inflammatory reactions around the subcutaneous injection site occur at the beginning of therapy regularly and are signs of the response situation of the patient. Transient, slight swellings of regional lymph nodes are also harmless phenomena. Fever induced by ISCADOR should not be repressed with antipyretics. Should fever last longer than 3 days the possibility of infectious processes or tumour fever must be taken into consideration. If fever increases over 38 °C/100.4 °F. (possibly with exhaustion, shivering, generally feeling unwell, headache and transient dizziness) or if local skin reactions exceed 5 cm in diameter, the next injection should only be given after these symptoms have abated and at a reduced strenath or dose. Local or systemic allergic or allergoid reactions may occur (normally as generalised pruritus, urticaria or exanthema, occasionally also with Quincke's oedema, chills, dyspnoea and bronchospasm, sporadically with shock or as erythema exsudativum multiforme which require discontinuation of the preparation and immediate medical treatment. Activation of previously existing inflammations as well as inflammatory irritations of superficial veins in the area of injection are possible. In such cases also a temporary discontinuation of treatment is necessary until the inflammatory reaction has abated. Chronic granulomatous inflammations (sarcoidosis, erythema nodosum) and autoimmune diseases (dermatomyositis) have been described during mistletoe therapy. Symptoms of increased intracerebral pressure during mistletoe therapy were also described in patients with brain tumours/brain metastases.

Pharmaceutical forms and packs: solution for injection in series packs: 2 x 7 ampoules à 1ml (bundle packaging). Series 0 also 1 x 7 ampoules à 1ml⁻¹). Solution for injection in single strength packs: 1 x 7 ampoules à 1ml.

Special precautions for storage: Store in a refrigerator at temperatures between + 2 °C and + 8 °C/35.6 °F. and 46.4 °F.

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1) not available in all countries

Note

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