ISCADOR®

Integrative Oncology

Recommendations

for treatment for professionals

ISCADOR AG

Integrative Oncology


with ISCADOR®

Content

This brochure is intended for medical professionals only. Please do not pass it on to patients.

The recommendations in this brochure are based on the product information submitted to the German Health Authorities.

About ISCADOR®

Active substance
ISCADOR contains as the active ingredient a fermented aqueous extract of the fresh mistletoe plant (*Viscum album* L.) from various host trees; in some cases with the addition of a metal salt.

Excipients
Aqua ad injectabilia, Natrii chloridum.

Galenic form
Ampoules containing 1ml for subcutaneous injection (s.c.).

Special precautions for storage
Store in a refrigerator at temperatures between + 2 °C and + 8 °C or 36 °F and 46 °F.

Host trees
Apple tree (Malus, M), oak (Quercus, Qu), pine (Pinus, P), elm (Ulmus, U).

Metal additions
Silver carbonate (Arg.), copper carbonate (Cu), mercury sulphate (Hg); whereas in the respective highest concentration of 20 mg/ml Iscador 2 x 10^{-5} parts of a D4 metal salt potency are added, i.e. less than 0.05% of the maximum tolerable daily dose of the respective chemical compound as defined by ICH Q3D.

Indication & Characteristics

Indication

According to the anthroposophic knowledge of the human being and nature.
This includes in adults:

Stimulation of the structuring and integrative forces for the purpose of elimination and reintegration of growth processes which have become independent, e.g.*:

- in malignant tumours, also with accompanying impairment of the hematopoietic organs
- in benign tumours
- in defined precancerous disorders
- with the aim to reduce the risk of tumour recurrence after surgery

* Authorised indications may differ depending on the registration in each country.

Characteristics

Clinical efficacy

In clinical studies, where it was used as a supportive treatment in addition to conventional oncological therapies, ISCADOR showed:

- improved quality of life, e.g. normalization of appetite, body weight, sleep and thermoregulation; elevation of mood and improvement of initiative [2, 7, 8, 12, 13, 22, 27, 29, 39, 42]
- reduction of adverse reactions to conventional oncological therapies such as chemo- and radiotherapy [2, 12, 22, 29, 39, 40]
- reduction of disease- or therapy-related symptoms such as nausea, vomiting, diarrhoea and immunodepression [2, 12, 29, 32, 39, 40, 47]
- mitigation of cancer-related fatigue (CRF) [2, 12, 29, 32, 39, 40, 47]
- relief of cancer-related pains [39, 42]
- reduction of hospitalization time [12, 29]
- improvement of immunological parameters including a reduced susceptibility to infections [5, 17, 19, 20, 21, 26, 30, 35]
- prevention of relapses and metastases [1, 12, 14, 15, 16]
- prolongation of survival [1, 2, 12, 13, 14, 29, 31, 41, 48]

Mode of action/pharmacodynamics

- Inhibition of tumour growth *in vitro* and *in vivo* [10, 34, 36]
- Improved immune function (immunomodulation) *in vitro* and *in vivo* [3]
- Enhanced DNA repair in healthy cells with protective effects against cytostatics- and radiation-induced DNA damage in healthy tissues *in vitro* and *in vivo* [4, 6, 23, 24, 25]

Practical use

Type of application

Subcutaneous (s.c.), preferably in the morning [18, 33, 43]. It is recommended to briefly warm up the cooled ampoule in the hand before use, and to rest for about 30 minutes after the injection. At least the 1st injection should be administered under medical supervision.

Injection site

If possible, near the tumour or metastasis, otherwise to alternating injection sites (e.g. abdomen or thigh and – except with mamma carcinoma – possibly upper arm). Injections into inflamed or irradiated skin should always be avoided.

ISCADOR® treatment

Treatment is divided into two phases. It begins with the initial phase of dose finding and then moves on to maintenance therapy. The initial phase can be divided into three steps:

1) Choice of ISCADOR preparation (see p. 8)
2) Start with ISCADOR Series 0 (see p. 10)
3) Gradual dose increase until the optimal response (see p. 12)

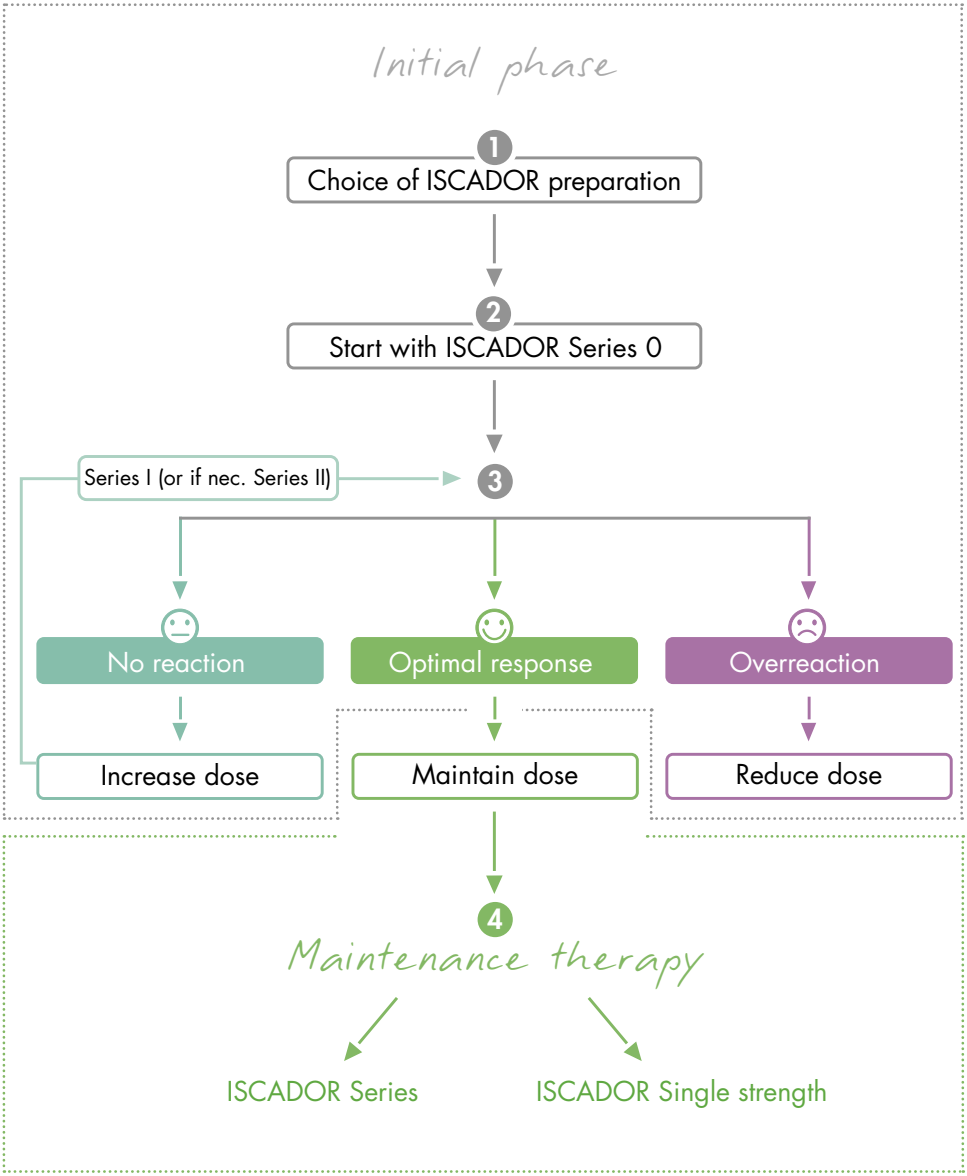
Once the patient displays an optimal dose response, the individual response dose has been determined and treatment moves into the phase of maintenance therapy. Maintenance therapy can either follow a rhythmically changing dosage regimen or use a single constant dosage (see p. 14).

Self-injection tutorial

Our video tutorial supports patients with their self-injections at home:
www.iscador.com/application

ISCADOR® treatment regimen

Initial phase up to the optimal individual response dose and moving on to maintenance therapy

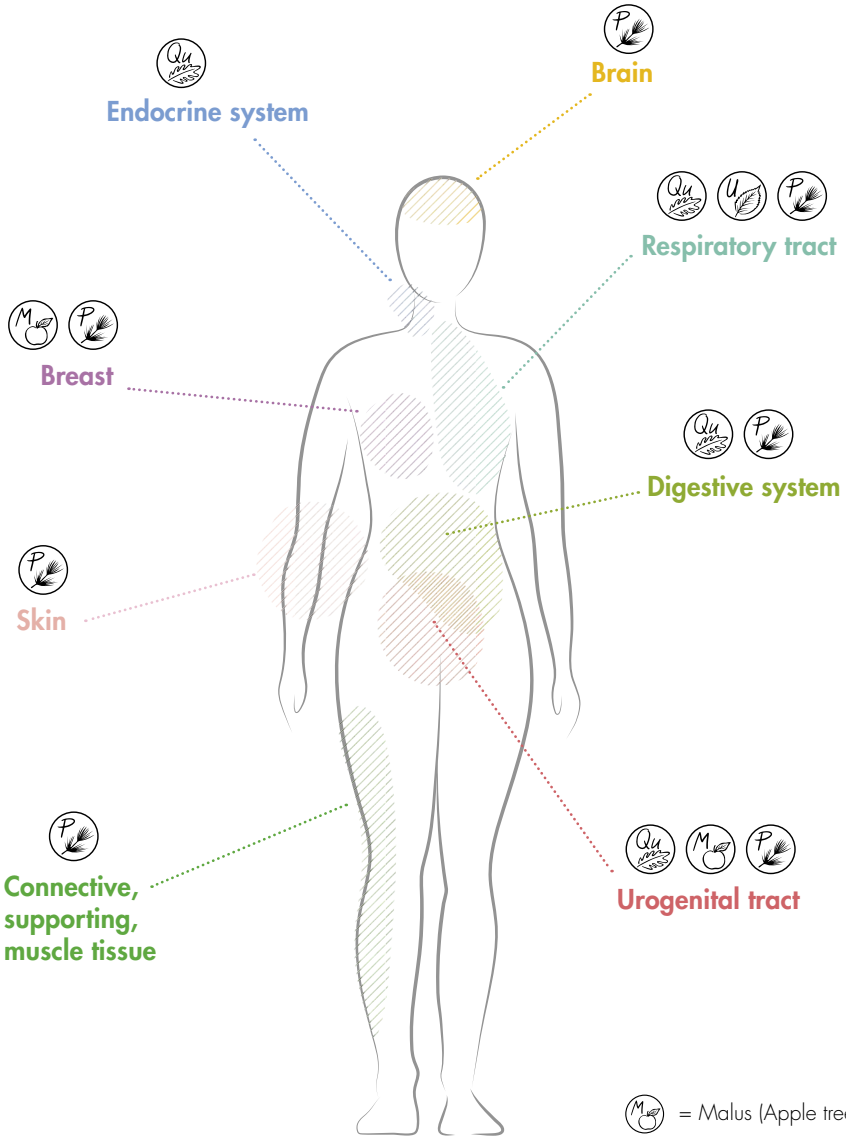


1 Choice of ISCADOR preparation

Based on clinical experience, different preparations are recommended depending on the location of the primary tumour. Packs of Series 0 are only available without metal salt addition, except ISCADOR U c. Hg.

Location of the primary tumour	**Recommendation**	**Alternative** In case of a suboptimal dose response (s. p. 12)
Digestive system		
Tongue, oral cavity, oesophagus	Qu	M
Stomach, liver, gall bladder, pancreas	Qu c. Cu	M c. Cu
Small intestine, large intestine, rectum	Qu c. Hg	M c. Hg
Anus	P	Qu
Urogenital tract		
Kidney	Qu c. Cu	M c. Cu
Bladder	Qu c. Arg.	M c. Arg.
Prostate, testes	Qu c. Arg.	M c. Arg.
Penis	P	Qu
Uterus, ovary	M c. Arg.	Qu c. Arg.
Vulva, vagina	M c. Arg.	P c. Hg
Cervix	M	Qu
Breast		
Pre-menopausal	M c. Arg.	P c. Hg
Peri-menopausal	M c. Hg	P c. Hg
Post-menopausal (also artificially induced)	P c. Hg	Qu c. Hg
Respiratory tract		
Nose, pharynx	P	P c. Hg
Larynx	Qu	P
Pleura	P	P c. Hg
Bronchia	U c. Hg*	Qu c. Hg
Endocrine system (thyroid)	Qu	P
Skin	P	P c. Hg
Connective, supporting, muscle tissue (sarcomas)	P	P c. Hg
Brain**	P	P c. Hg

* ISCADOR U is only available with metal addition (U c. Hg).
** Only according to strict indication and under close clinical control.



Recommendation for the choice of ISCADOR preparation. Alternative in case of not optimal reaction see table on the left.

= Malus (Apple tree)
= Pinus (Pine)
= Quercus (Oak)
= Ulmus (Elm)

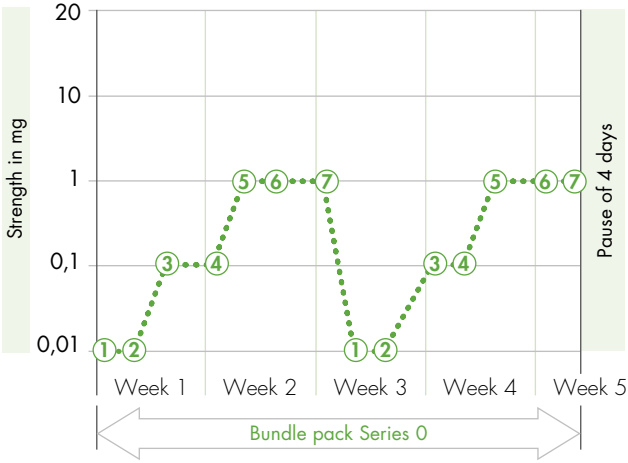
2 Start with ISCADOR Series 0

After choosing the ISCADOR preparation, treatment is started with a bundle pack of ISCADOR Series 0 (2 x 7 ampoules; see also right page).
The gradually increasing dosage can prevent overreactions. 1 ml ISCADOR is injected subcutaneously 2 to 3 times a week with increasing strength according to the composition of the Series.

The response to the last three ampoules of the serial pack determines the further procedure.

Rhythmical dosage

Example: Three injections per week with a bundle pack Series 0



	1st pack							2nd pack							
Ampoule No.	1	2	3	4	5	6	7	1	2	3	4	5	6	7	–
Weekday (for example)	Mo	We	Fr	Mo	We	Fr	Mo	We	Fr	Mo	We	Fr	Mo	We	–
Week	Week 1			Week 2			Week 3			Week 4			Week 5		

Pauses: Pause of 4 days after a bundle pack.

ISCADOR® Series pack

One Series pack contains 7 ampoules in increasing dose strength.
The numbers inside the box indicate the order in which the ampoules have to be injected.
The Series packs are also available as so-called bundle packs containing 2 Series packs of 7 ampoules each.

Series 0	
Ampoule No.	Strength
1	0,01 mg
2	0,01 mg
3	0,1 mg
4	0,1 mg
5	1 mg
6	1 mg
7	1 mg

Series I	
Ampoule No.	Strength
1	0,1 mg
2	0,1 mg
3	1 mg
4	1 mg
5	10 mg
6	10 mg
7	10 mg

Series II	
Ampoule No.	Strength
1	1 mg
2	1 mg
3	10 mg
4	10 mg
5	20 mg
6	20 mg
7	20 mg

3 Gradual dose increase until the optimal response

No reaction

None of the reactions described in the following section «Optimal response» occurs

➔ **Increase dose:** Change to next higher Series

No reaction until ampoule 7 of Series II:

Check the section «Optimal response» below for further signs of successful dose finding, as not every patient develops a local reaction. Complete absence of any reaction mentioned below may warrant a change in host tree preparation.

Our Infoline for medical professionals will be happy to provide you with information.

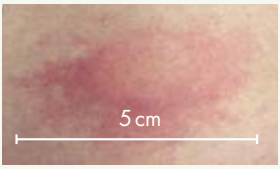
Optimal response

Signs of optimal response (individually or in combination):

Improvement of the subjective state of health like increase in appetite, sleep quality, sensation of warmth, performance, mental state and reduction of pain

Increase of body temperature within about 5 hours after injection (< 38 °C)

Local inflammatory reaction at the injection site with a maximum diameter of 5 cm (2 inches), including induration, itching, swelling and/or local hyperthermia, which generally disappears spontaneously after one or two days. The absence of a local reaction is not a sign of reduced efficacy.



Typical local reaction

➔ **Maintain dose:** Continue with maintenance therapy (see p. 14)

Fatigue, shivering, general indisposition, headache or temporary dizziness occuring on the day of injection are not necessarily signs of intolerance but may indicate that the last administered dose was too high and must be adjusted.

Overreaction

Febrile, inflammatory states with body temperatures over 38 °C (100.4 °F)

Local inflammatory reactions at the injection site > 5 cm or 2 inch Ø

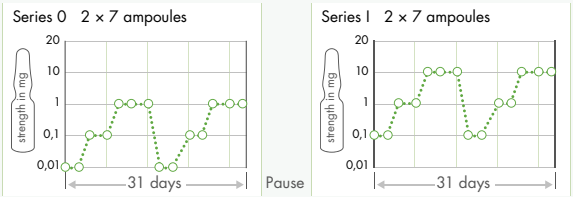
Lassitude, shivering, general feeling of unwellness, headaches and dizziness that occur on the day of the injection and exceed a tolerable level or that have not subsided by the following day

➔ **Reduce dose:** Pause treatment until symptoms have resolved, then switch to the next lower Series.

In case of an overreaction with Series 0, please contact our Infoline (see p. 15).

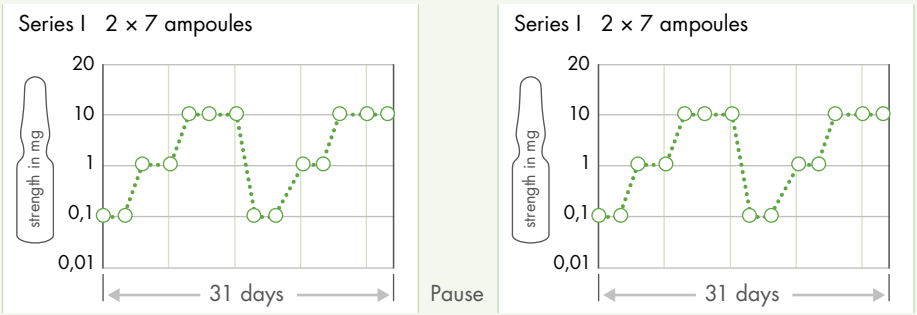
Example no reaction*

Change to the next higher Series:
Series 0 ➔ change to Series I



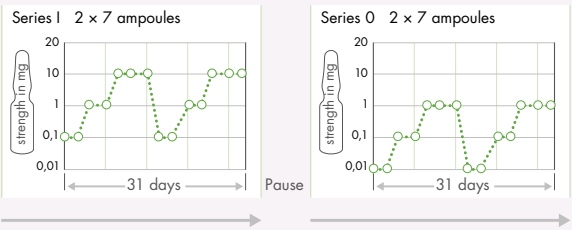
Example optimal response*

Series maintained:
Series I ➔ maintain Series I



Example overreaction*

Change to next lower Series:
Series I ➔ change to Series 0



○ = ampoule * to the last three ampoules of the Series pack

4 Maintenance therapy

If the patient shows an optimal reaction to the last three ampoules of a Series, the correct dose has been determined and maintenance therapy can be started. This means that the determined dose is now applied until the patient no longer shows an optimal reaction or the therapy is terminated.
The dosage should be reviewed every 3 – 6 months based on patient response and clinical development. Since it is to be expected that the local reaction weakens over the course of therapy or disappears altogether, a change to an ISCADOR preparation of a different host tree can be considered in such a case. Our Infoline for medical professionals can support you in this process.
A maintenance therapy can be carried out with rhythmical changing or constant dosage:

Rhythmical dosage with ISCADOR Series

Continue with the Series that is able to elicit an optimal reaction.
Due to the different strengths within the Series pack, lower concentrations alternate with the maximum tolerated dose. Clinical experience has shown that the rhythmical dosage regimen can stimulate the body's auto-regulation and prevent habituation.
Series packs are mainly used in a curative setting and are suitable as a supportive treatment in phases of recurrence prophylaxis.

Constant dosage regimen with ISCADOR Single strength packs

Within a Single strength pack, all ampoules contain the same dosage. The number in mg indicates the amount of fresh plant material contained in the extract inside the ampoule. The Single strength pack is chosen to match the patient's optimal individual dose response. If, for example, the patient responds to the last three ampoules of Series I, the Single strength pack of 10 mg is selected for maintenance therapy. Treatment with a single strength regimen can help strengthen weakened patients and is mainly used in a palliative situation, e.g. with an inoperable or incompletely removed tumour or advanced metastasis). It may also be used in the rare case of the highest dose in a Series eliciting an overreaction, while the next lower Series is considered insufficient. Example: at an overreaction at 10 mg in Series I, change to a constant regimen with ISCADOR 5 mg special).

Treatment pauses

In case of a favourable course of treatment, pauses of 1–2 weeks may be introduced after each course of 14 ampoules. From the third treatment year onwards, pauses may be extended to 2–3 weeks at a time.
As mentioned above, a therapy with constant doses should primarily be used in a palliative setting. Here it is recommended to continuously maintain the therapy without breaks.

Duration of treatment

Principally, duration of treatment is not limited. It depends on the respective risk of relapse and the patient's individual condition, prognosis and preference. In most cases, this means a continuation of the therapy for approx. 5 years or possibly longer from the time of diagnosis or from the beginning of the curative primary therapy [2, 12].

We are at your service!

Our Infoline for medical professionals

Phone (* free of charge)

* CH, FL: 0800 706 700

* DE: 0800 706 7000

* AT, FR, IT, NZ, SE, UK: 00800 706 70000

All other countries: +49 7621 162 26 00

E-mail: infoline@iscador.com

Restrictions on use

Contraindications

- Known allergy to preparations of European mistletoe (*Viscum album* L.)
- Acute inflammatory conditions accompanied by high fever with temperatures > 38°C. Treatment should be paused until the signs of acute inflammation have subsided.
- Chronic granulomatous disorders, florid autoimmune disorders and conditions under immunosuppressive therapy.
- Hyperthyroidism with tachycardia

Undesirable effects

Activation of preexisting inflammatory conditions is possible. In such cases, treatment should be paused until the inflammation subsides. Localized or systemic allergic reactions up to anaphylaxis have been reported, usually in the form of generalised itching, urticaria or exanthema, sometimes with angioedema, shivering attacks, shortage of breath and bronchospasms, sporadically with shock or as erythema exsudativum multiforme), requiring discontinuation of the preparation and initiation of emergency medical treatment.

Interactions

Due to the fast evolution of oncological treatments, knowledge about interactions of ISCADOR with other pharmaceuticals is limited. In vitro examinations [9, 11, 28, 44, 45, 46] as well as clinical studies [37, 38, 40] have found no evidence for potential interactions. Long-term clinical experiences confirm this.

The approved drug information has been published on www.pharmnet.bund.de.

ISCADOR® Product range

Host tree	ISCADOR	Series Bundle pack (2 x 7 ampoules, Series 0 also 1 x 7 ampoules)			Single strength packs Pack (1 x 7 ampoules)							
		Series 0	Series I	Series II	0,0001mg	0,001mg	0,01mg	0,1mg	1mg	5 mg	10 mg	20 mg
Malus Apple tree	M											
	M c. Arg.[1]											
	M c. Cu[2]											
	M c. Hg[3]											
	M spez.[4]											
Quercus Oak	Qu											
	Qu c. Arg.[1]											
	Qu c. Cu[2]											
	Qu c. Hg[3]											
	Qu spez.[4]											
Pinus Pine	P											
	P c. Hg[3]											
Ulmus Elm	U c. Hg[3]											

[1] as silver carbonate [2] as copper carbonate [3] as mercury sulphate (Metal salt addition of 2 x 10^{-5} parts of a D4 potency in 20 mg/ml)

[4] spez. = spezial: with constant quantity of substances typically found in mistletoe, also available as pack with 2 x 7 ampoules


ISCADOR®
ISCADOR AG

Our Services

We are at your service

Infoline for medical professionals

We are at your disposal for professional advice on the use of ISCADOR in integrative cancer treatment and for medical and scientific consultation:

Phone (free of charge)

CH, FL: 0800 706 700

DE: 0800 706 7000

AT, FR, IT, NZ, SE, UK: 00800 706 70000

All other countries:

Phone +49 7621 162 26 00

E-mail: infoline@iscador.com

Online-services on www.iscador.com

Browse through our website for more information on integrative cancer treatment, our company and much more.

Additional scientific information and documents are available in the professionals section on our website: **www.iscador.com/professionals**

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ISCADOR® solution for injections
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 understanding of human being and nature. This includes in adults: 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 diseases treated with immunosuppressive drugs. Hyperthyroidsm with tachycardia.
Side effects: ocally restricted inflammatory reactions around the subcutaneous injection site, fever, flu-like symptoms, swellings of regional lymph nodes as well as activation of inflammations/allergic reactions. The occurrence of chronic granulomatous inflammation, autoimmune diseases and symptoms of an increase in brain pressure in brain tumors/metastases during mistletoe therapy have also been reported.
Pharmaceutical forms and packs: solution for injection in Series packs:
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