

# ISCADOR®

Integrative Oncology



## *Recommendation*

for treatment for professionals

ISCADOR  AG





*with ISCADOR®*

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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 1 ml 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);  
0.001 µg of the corresponding metal is added to 10 mg mistletoe extract.



# Indication & Characteristics

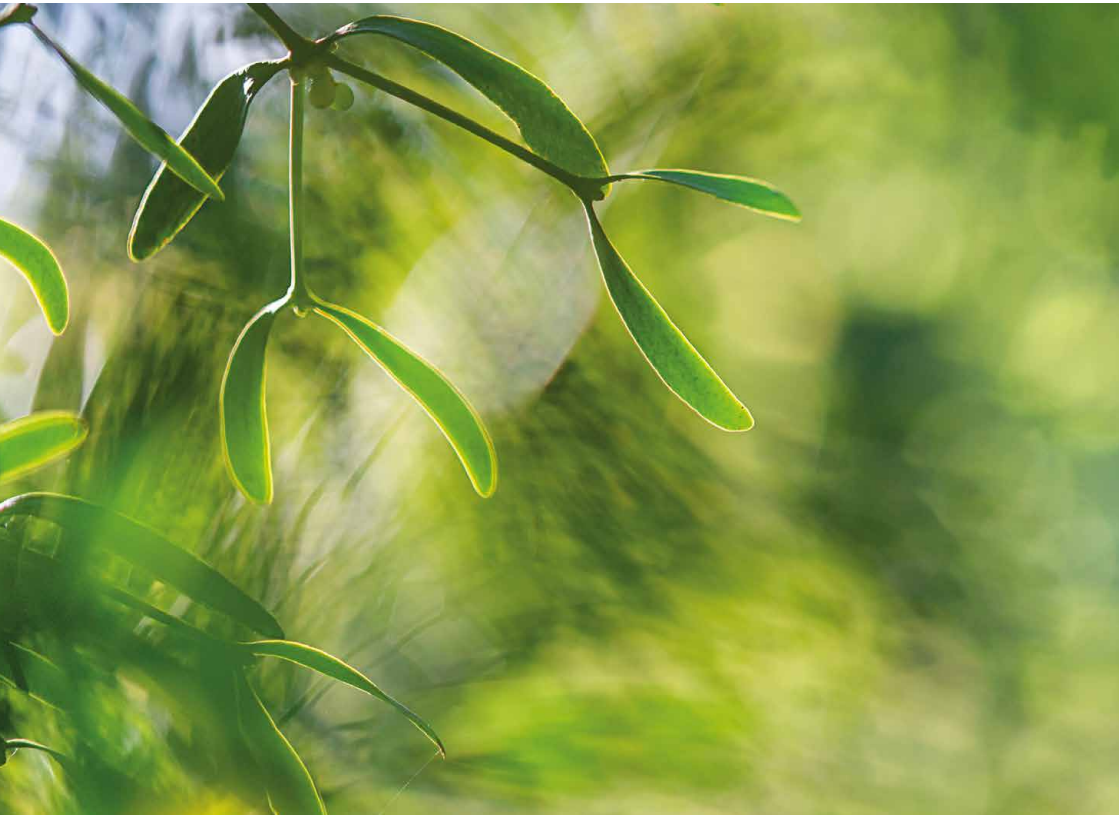
## Indication

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

Stimulation of the forming and integration 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 hematopoietic organs
- in benign tumours
- in defined precancerous disorders
- for reducing the risk of tumour recurrence after surgery

\* Authorised indications may differ from the above given indications depending on the country.



# Characteristics

## Clinical efficacy

In clinical studies in the course of a supportive treatment in addition to a conventional adjuvant oncological therapy ISCADOR showed:

- an improvement in quality of life induced by an increase in appetite and body weight, a normalisation of sleep and thermoregulation as well as an improvement of the mood and taking initiative <sup>2, 7, 8, 12, 14, 23, 30, 37, 40</sup>
- a reduction of adverse drug reactions due to conventional therapies such as chemo- and radiotherapy <sup>2, 12, 23, 30, 37, 38</sup>
- a reduction of disease- or therapy-related symptoms such as nausea, vomiting, diarrhoea and immunodepression <sup>2, 12, 28, 30, 37, 39, 40</sup>
- a mitigation of cancer fatigue syndrome <sup>2, 12, 30, 37, 40, 46</sup>
- a relief of cancer-related pains <sup>37, 40, 41</sup>
- a reduction of hospitalization time <sup>12, 30</sup>
- an improvement of the immunological reaction such as an increase of body's natural defences and a decrease in susceptibility to infections <sup>5, 18, 20, 21, 22, 27, 35, 41</sup>
- a prevention of relapses and metastases <sup>1, 12, 15, 16, 17</sup>
- a prolongation of survival <sup>1, 2, 12, 14, 15, 30, 31, 39, 47</sup>

## Mode of action/pharmacodynamics

- Inhibition of tumour growth without causing damage to healthy tissue *in vitro* and *in vivo* <sup>10, 34, 36</sup>
- Improvement of defence forces (immunomodulation) *in vitro* and *in vivo* <sup>3</sup>
- Protective effect on healthy cells with regard to cytostatics- and radiation-induced DNA damage *in vitro* and *in vivo* (DNA repair) <sup>4, 6, 24, 25, 26</sup>

# Practical use

## Type of application

Subcutaneous (s.c.), preferably in the morning<sup>19, 33, 42</sup>. It is recommended to briefly warm up the cooled ampoule in the hand before use. After the injection, rest for about 30 minutes. At least the 1st injection should be given in the practice.

## Place of application

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

## The therapy with ISCADOR®

The therapy 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 page 8)
- 2) Start with ISCADOR series 0 (see page 10)
- 3) Gradual dose increase until the optimal response (see page 12)

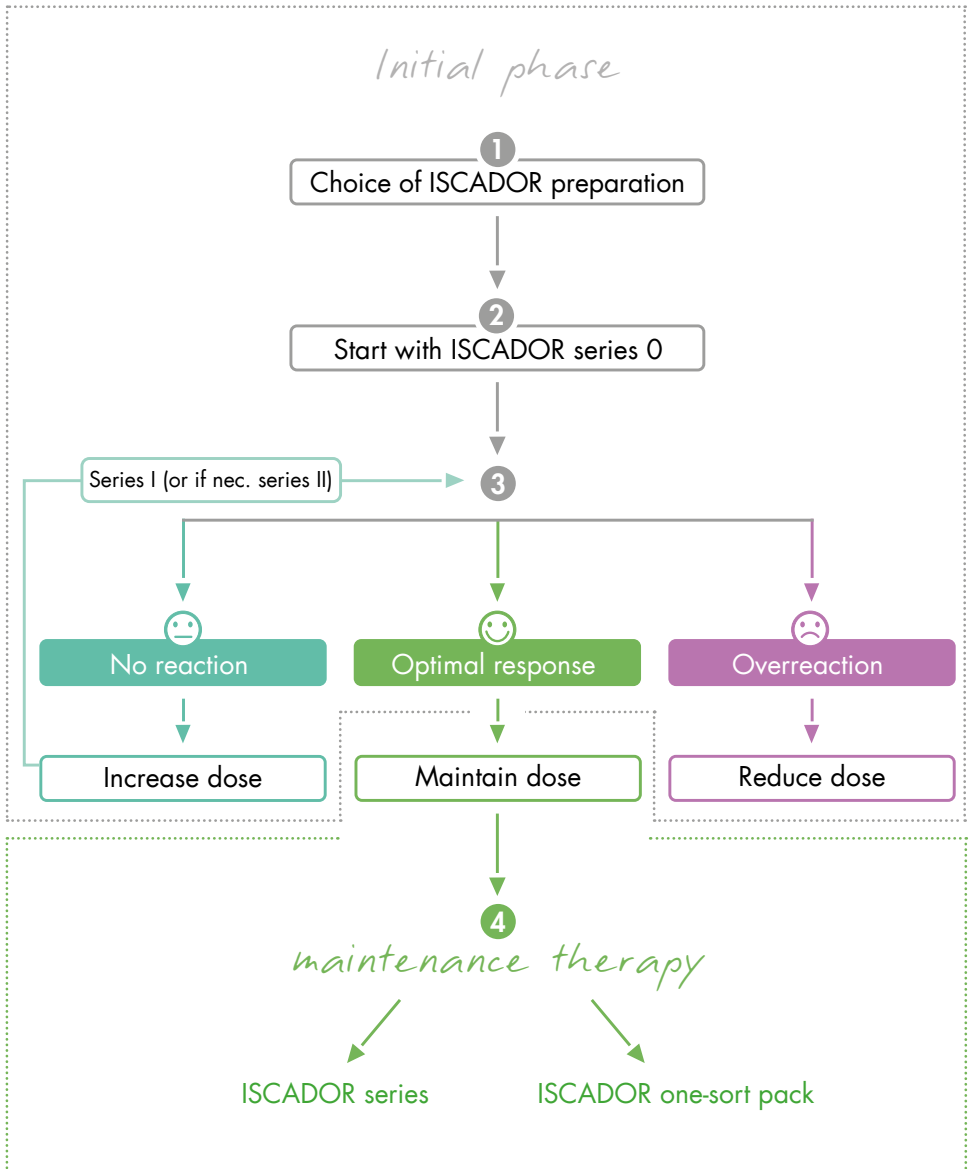
If the patient shows an optimal response, the individual response dose has been determined and maintenance therapy can begin. The maintenance therapy can be carried out with rhythmically changing or constant dosage. More on this from page 14.





# ISCADOR® therapy regimen

Initial phase up to the individual reaction dose and recommended maintenance therapy



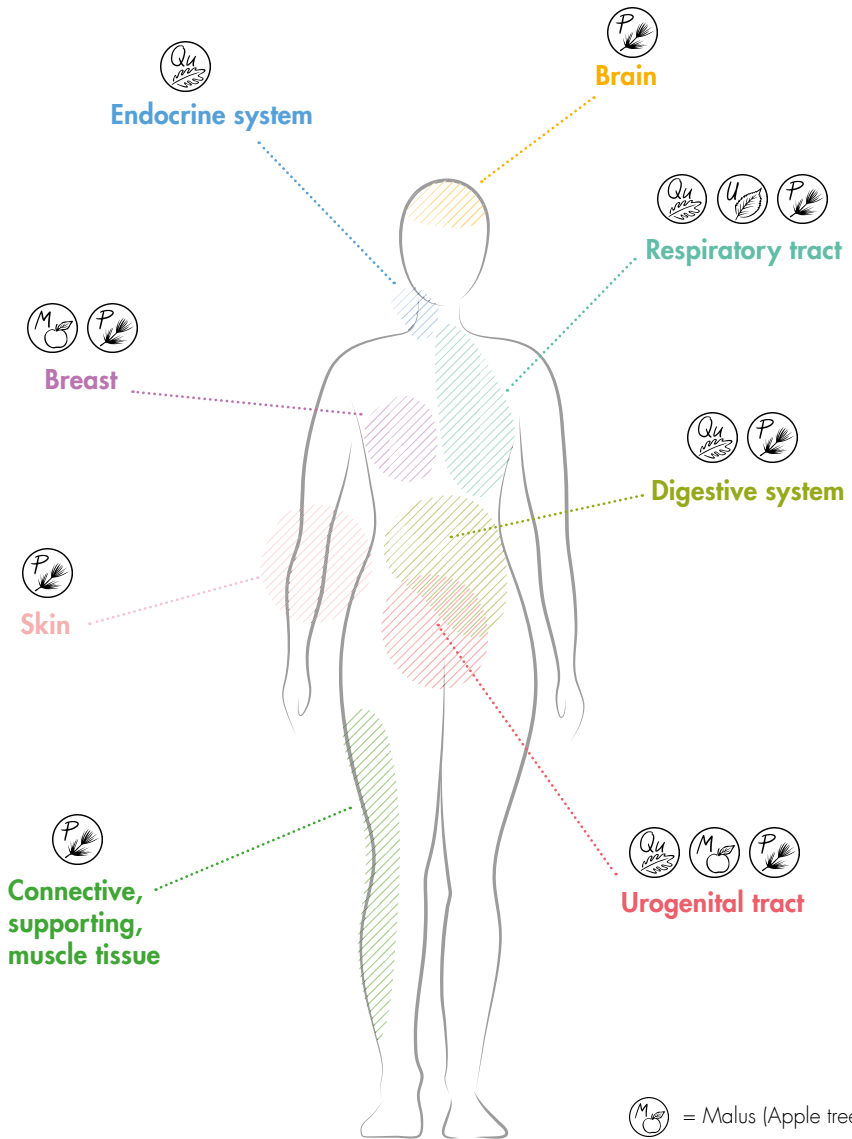
# 1 Choice of ISCADOR preparation

Based on experience, different preparations are recommended depending on the location of the primary tumour. Packs of series O 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)
<b>Digestive system</b>		
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
<b>Urogenital tract</b>		
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	P
<b>Breast</b>		
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
<b>Respiratory tract</b>		
Nose, pharynx	P	P c. Hg
Larynx	Qu	P
Pleura	P	P c. Hg
Bronchia	U c. Hg*	Qu c. Hg
<b>Endocrine system (thyroid)</b>		
	Qu	P
<b>Skin</b>		
	P	P c. Hg
<b>Connective, supporting, muscle tissue (sarcomas)</b>		
	P	P c. Hg
<b>Brain**</b>		
	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

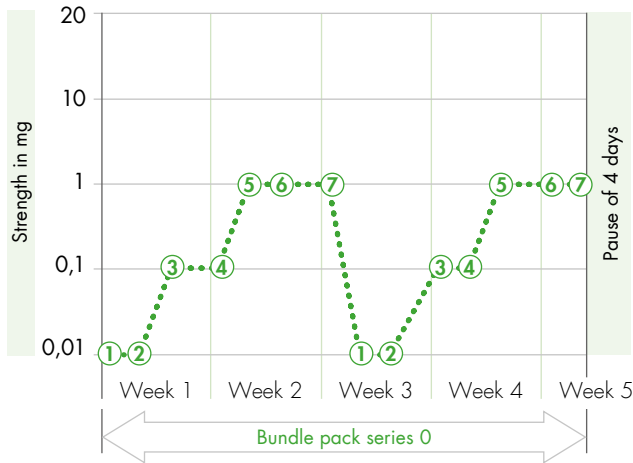
After choosing the ISCADOR preparation, the therapy is started with a bundle pack of ISCADOR series 0 (2 x 7 ampoules; see also right page).

The gradually increasing dosage is intended to 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



	1 <sup>st</sup> pack							2 <sup>nd</sup> 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 serial 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 available on the market in a so-called bundle pack (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

### Change of the ISCADOR preparation:



Since it is to be expected that the local reaction will weaken or even disappear completely with longer therapy duration, a switch to an ISCADOR preparation from another host tree can be considered.



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



### Optimale 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 site of subcutaneous injection with a maximum diameter of 5 cm or 2 inch (induration, itching, swelling 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 picture of a local reaction

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

Lassitude, shivering, a general feeling of unwellness, headache and temporary dizziness which may occur on the same day as the injection are not signs of general intolerance, but indicate that an effective but possibly already too high dose has been administered.



### 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

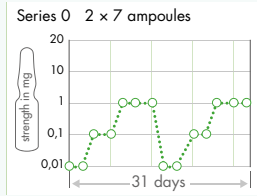
→ **Reduce dose:** Interruption of therapy until symptoms resolved and then switch to the next lower series



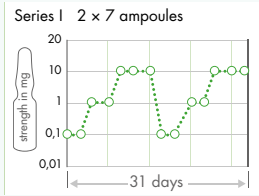
In case of an overreaction with series 0, please contact our Infoline (see p. 15).

### ☹ Example no reaction\*

Change to the next higher series:  
Series 0 → change to series I

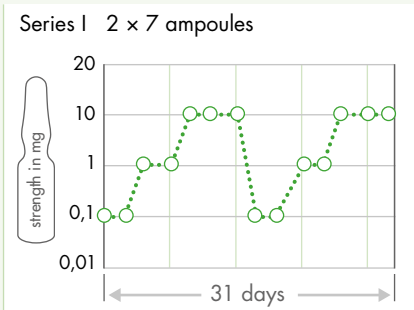


Pause

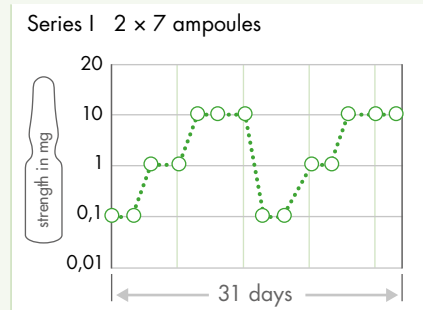


### 😊 Example optimal response\*

Series maintained:  
Series I → maintain series I



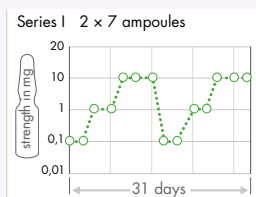
Pause



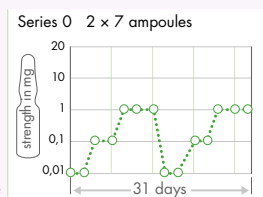
Maintenance Therapy

### ☹ Example overreaction\*

Change to next lower series:  
Series I → change to series 0



Pause



○ = ampoule

\* to the last three ampoules of the serial 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 checked at intervals of 3–6 months based on the patient's response and tumour behaviour.

A maintenance therapy can be carried out with rhythmical changing or constant dosage:

### Rhythmical dosage with ISCADOR series

Remain with the series where an optimal reaction occurred.

Due to the different strengths within the series package, lower concentrations alternate with the maximum tolerated dose. Decades of experience have shown that a rhythmical dosage can strengthen the «solidified» self-regulating forces of the organism again and prevent a habituation effect.

Series are mainly used in the adjuvant situation (completely removed tumour, no metastasis).





## Constant dosage with ISCADOR one-sort pack

Within a one-sort pack, all ampoules have the same strength. The strength in mg indicates the amount of fresh plant extract per ampoule. The one-sort pack is chosen to match the individual response dose. If, for example, the patient responds to the last three ampoules of series I, the one-sort pack of 10 mg is selected for maintenance therapy.

Application with an ongoing constant concentration can strengthen the patient. The therapy with one-sort packs is mainly used in a palliative situation (inoperable or incompletely removed tumour, advanced metastasis). It is also used if an overreaction occurs at the highest concentration level of the respective series and a continuation with the next lower series is considered insufficient (e.g. overreaction at 10 mg from series I → transition to ISCADOR 5 mg special).

## Treatment pauses

In the case of a positive course of treatment, with rhythmical dosage, pauses of 1–2 weeks after  $2 \times 7$  ampoules can be introduced. If the duration of treatment is longer, the breaks can be extended from the 3rd year of treatment.

## Duration of treatment

In principle, the duration of application is not limited. It is determined individually and depends on the respective risk of relapse and the individual condition or diagnosis of the patient. 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 <sup>2, 12</sup>.

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](mailto:infoline@iscador.com)





# Restrictions on use

## Contraindications

- Known allergy to preparations of European mistletoe (*Viscum album* L.)
- Highly febrile or (acute) inflammatory disorders with temperatures above 38 °C. Treatment should be interrupted until the signs of inflammation have subsided.
- Chronic granulomatous disorders, florid auto-immune disorders and ones under immune-suppressive therapy
- Hyperthyroidism with tachycardia

## Undesirable effects





An activation of previously existing inflammations is possible. In such cases, a temporary pause of treatment is necessary until the inflammatory reaction subsides. Localised or systemic allergic or allergoid reactions may occur (usually in the form of generalised itching, urticaria or exanthema, sometimes with Quincke's oedema, 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

So far, interactions with other pharmaceuticals such as cytostatics or monoclonal antibodies have only been investigated in a few cases. There was no evidence for potential interactions in *in vitro* examinations<sup>9, 11, 29, 32, 43, 44, 45</sup> and in one clinical study<sup>38, 48, 49</sup>. Long-term clinical experiences also confirm this.

The approved drug information has been published on [www.pharmnet.bund.de](http://www.pharmnet.bund.de).

# ISCADOR® Product range

Host tree	ISCADOR	Series		One-sort packs (single strength) pack (1 x 7 ampoules)								
		Series 0 bundle pack (2 x 7 ampoules, Series 0 also 1 x 7 ampoules)	Series I	Series II	0,0001mg	0,001mg	0,01mg	0,1mg	1mg	5mg	10mg	20mg
 <b>Malus</b> Apple tree	M											
	M c. Arg. <sup>1</sup>											
	M c. Cu <sup>2</sup>											
	M c. Hg <sup>3</sup>											
	M spez. <sup>4</sup>											
 <b>Quercus</b> Oak	Qu											
	Qu c. Arg. <sup>1</sup>											
	Qu c. Cu <sup>2</sup>											
	Qu c. Hg <sup>3</sup>											
	Qu spez. <sup>4</sup>											
 <b>Pinus</b> Pine	P											
	P c. Hg <sup>3</sup>											
 <b>Ulmus</b> Elm	U c. Hg <sup>3</sup>											

<sup>1</sup> as silver carbonate <sup>2</sup> as copper carbonate <sup>3</sup> as mercury sulphate (Metal addition of 0.0002 parts as irriuration in a potency D4)

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



# Our Services

## We are at your service

### Our 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](mailto:infoline@iscador.com)

## Online-services on [www.iscador.com](http://www.iscador.com)

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

### Medical directory

Are you an expert in the field of integrative tumour treatment, especially in mistletoe therapy? Then we would be pleased if you register online in our specialist directory. This will enable patients to find you at [www.iscador.com/find-specialists](http://www.iscador.com/find-specialists) as a provider of integrative cancer therapy with ISCADOR.



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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. Hyperthyroidism with tachycardia.

**Side effects:** locally 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: 2 x 7 ampoules cont. 1 ml (bundle pack), series 0 also 1 x 7 ampoules cont. 1 ml. Solution for injection in single strength packs: 1 x 7 ampoules cont. 1 ml, Iscador special also 2 x 7 ampoules cont. 1 ml (bundle pack).  
Iscador AG, Spitalstr. 22, 79539 Lörrach

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