Package leaflet: Information for the user

Isorel® A (Abietis) solution for injection

Active substance: *Aqueous fresh plant extract of fir mistletoe*

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Isorel A (Abietis) is and what it is used for

Isorel A (Abietis) is an aqueous fresh plant extract of fir mistletoe.

Indication: As a support in addition to general measures, to improve quality of life with breast and intestinal cancer during and after standard therapy.

Your doctor will decide which Isorel-preparation you should use.

This medicine is used for adults aged 18 years and older.

2. What you need to know before you use Isorel A (Abietis)

Do not use Isorel A (Abietis)
- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6);
- if you suffer from an acute inflammatory or febrile illness with fever exceeding 38°C. An ongoing treatment with Isorel A (Abietis) should be paused until the illness has subsided.

Warnings and precautions
Talk to your doctor before using Isorel A (Abietis).

Take special care when using Isorel A (Abietis)
- if you are hypersensitive to preparations containing mistletoe. In these cases, treatment is only possible after successful desensitization treatment (see section 3) with a gradually increasing dose. Please consult your doctor first.
- if you are prone to vein inflammation, the injections should be given only in areas not at risk of inflammation.
- if you suffer from severe hyperthyroidism, you need to increase the dose more slowly.
- if you are receiving radiotherapy, Isorel A (Abietis) should not be injected into radiation areas.

Children and adolescents
Use for children and adolescents under 18 years of age is not recommended due to insufficient data.

Other medicines and Isorel A (Abietis)
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, including over-the-counter medicines.

Isorel A (Abietis) should not be mixed with other medicines in the same syringe.

If you use Isorel A (Abietis) during chemotherapy, hormone or radiation therapy, you may need to reduce the dose, depending on your reaction. Speak with your doctor.

No interaction studies have been performed.

To date no interactions have been reported.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

As the data available is insufficient, it is not recommended to use this medicine during pregnancy and when breast-feeding.

Driving and using machines

No studies have been performed on how this medicine affects the ability to drive and use machines.

Isorel A (Abietis) contains sodium.
This medicine contains less than 1 mmol sodium per ml, that is to say essentially 'sodium-free'.

3. How to use Isorel A (Abietis)

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Generally, treatment with Isorel A (Abietis) should always be overseen by a doctor who will also determine the optimal dose for you.

Method of administration:
Subcutaneous or intramuscular (injection).

Isorel A (Abietis) can be injected either under the skin (subcutaneously) or into muscle tissue (intramuscular).

Unless specified otherwise by the doctor, the standard dose should be administered as follows; there is a difference between the initial and the treatment phase.

Initial phase
A usual **initial treatment** begins with serial pack I. It contains the strengths 1, 6, 12, 24 and 36 in ascending concentration.

Serial packs II and III are available for hypersensitive patients (**desensitization treatment**). These contain strengths 1, 6, 12, 24, 36 and 60 in slowly increasing concentration series.
Injections are usually given 3 times per week, up to 1 ampoule per day, in accordance with ampoule assembly of the corresponding pack, working from left to right or from the lower to the higher strength.

Treatment phase
After completion of the initial phase, the transition to the therapy phase with strength 60 takes place, taking into account the optimal individual dosage in consultation with your doctor.

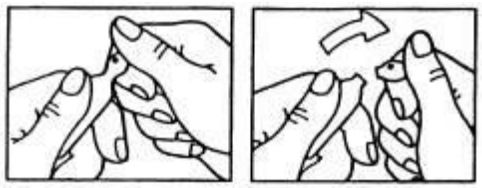
A dose of strength 60 is injected - usually 3 times a week, up to daily injections of 1 to no more than 3 ampoules.

Maximum daily dose
The maximum daily dose and maximum single dose for subcutaneous and intramuscular injection is 3 am of strength 60. This corresponds to a maximum daily dose of 180 mg.

Use in children and adolescents
Isorel A (Abietis) is not recommended for use in children and adolescents below 18 years due to insufficient data.

Duration of use
You doctor decides for how long you use the medicine, which will depend on your condition. Treatment usually lasts several years and there is, in principle, no limitation, with a possibility of longer breaks as treatment continues.

Instructions for use
Isorel A (Abietis) is packed in easy-to-open breakpoint ampoules: Point the tip up, tap to encourage the liquid to flow down and open the ampoule by bending the head of ampoule backwards, applying gentle pressure.



If you use more Isorel A (Abietis) than you should
Usually, no changes will occur. However, if you do notice severe local reactions at the injection site (red patches larger than 5 cm), fever higher than 38°C or flu-like symptoms, please contact your doctor.

Information for the doctor
You can find information on overdose at the end of this leaflet.

If you forget to use Isorel A (Abietis)
Do not take a double dose to make up for a forgotten one.
Continue the treatment as scheduled with the next (forgotten) dose.

If you stop using Isorel A (Abietis)
Please discuss this with your doctor.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Important signs to look out for and action to take if you are affected
Localized inflammation at the injection site (less than 5 cm, with mild itching) or a brief increase of temperature between 1°C to 1.5°C are **not a concern**.

If inflammation at the injection site produces patches larger than 5 cm, if your temperature rises by 1°C to 1.5°C for more than 1-2 days, if any fever rises above 38°C, or if you experience flu-like symptoms, stop using Isorel A (Abietis) and contact your doctor.

Although no cases of severe allergic reactions (anaphylactic shock) have been reported for Isorel A (Abietis), they cannot be completely ruled out due to the natural biological origin of the medication. If you do experience widespread itchy rashes all over the body, shortness of breath, sudden chills, swelling of the face, circulatory insufficiency and/or other signs of collapse, stop taking Isorel A (Abietis) immediately and **contact your doctor as soon as possible**.

Information for the doctor:
Allergic reactions should be treated in accordance with clinical symptoms.

Possible side effects
This section provides information on side effects and their frequency. Frequency is rated as follows:

Very common	*may affect more than 1 in 10 people*
Common	*may affect up to 1 in 10 people*
Uncommon	*may affect up to 1 in 100 people*
Rare	*may affect up to 1 in 1 000 people*
Very rare	*may affect up to 1 in 10 000 people*
Not known	*cannot be estimated from the available data*

General disorders and administration site conditions and skin and subcutaneous tissue disorders ("local reaction")
Very common, especially if Isorel A (Abietis) is injected under the skin, is temporary localised reddening at the injection site, with or without swelling, of about 1 cm to 5 cm in diameter, which may occur within 24 hours after administration when starting treatment or when increasing the dose.
These reactions are **not a concern** but you should change the injection site.

In case of *uncommon* severe local reactions (red patches larger than 5 cm), treatment should be paused and the dose reduced temporarily after the symptoms have disappeared.
If this is not successful, a **desensitization treatment** must be completed using the serial packs II and III (see section 3). If this does not yield any success, either, it may help to switch from Isorel A (Abietis) to another Isorel preparation: Isorel P (Pini) or Isorel M (Mali) in coordination with your doctor - starting with desensitization treatment.

Vascular disorders
Rarely, localised inflammation and irritation of veins can occur (vein inflammation). It may be appropriate to pause therapy in such cases.

Increased temperature
The *commonly* occurring increase of temperature by 1° C.-1.5° C is harmless. The temperature usually normalises after 1-2 days and does not require any special treatment.
Fever caused by Isorel A (Abietis) should not be treated with antipyretic drugs. However, it is recommended to wait for the temperature to fall before continuing the treatment. Increase the dose more slowly in this case.

If your temperature increases for more than 1-2 days or if your temperature rises above 38°C, please inform your doctor so that he can arrange tests for inflammatory diseases, if necessary.

Immune system disorders
In contrast to the localised reactions described above, the *rarely* seen allergic reactions to mistletoe preparations can be identified by the immediate appearance of generalised skin reactions (redness across the whole body, itchy rashes, swelling of the face). If you experience such symptoms, contact your doctor immediately.

In such cases, treatment should be paused and a **desensitization treatment** using serial packs II and III

should be completed once the symptoms have disappeared (see section 3). If this does not yield any success, either, it may help to switch from Isorel A (Abietis) to another Isorel preparation: Isorel P (Pini) or Isorel M (Mali) in coordination with your doctor - starting with desensitization treatment.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

Bundesamt für Sicherheit im Gesundheitswesen
Traisengasse 5
1200 VIENNA
AUSTRIA
Fax: + 43 (0) 50 555 36207
Website: http://www.basg.gv.at/

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Isorel A (Abietis)

Store in a refrigerator (2°C - 8°C).
Do not freeze.
Store in the original package in order to protect the medicine from light.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton or on the container after "verwendbar bis".
The expiry date refers to the last day of that month.

Information on shelf life once opened
The ampoules should be used immediately after opening. Any unused medicine must be discarded immediately and must not be used at a later time as the contents of the ampoule may no longer be sterile.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Isorel A (Abietis) contains

- The active substance is: extract of fresh European mistletoe

One ampoule (1 ml) contains:

Strength 1
17 mg extract of fresh European mistletoe (*Viscum album subsp. abietis,* plant to extract ratio = 1:15 - 1:16.3; extractant: water for injections, isotonised).

Strength 6
101 mg extract of fresh European mistletoe (*Viscum album subsp. abietis,* plant to extract ratio = 1:15 - 1:16.3; extractant: water for injections, isotonised.

Strength 12
202 mg extract of fresh European mistletoe (*Viscum album subsp. abietis,* plant to extract ratio = 1:15 - 1:16.3;

extractant: water for injections, isotonised).

Strength 24
403 mg extract of fresh European mistletoe (*Viscum album subsp. abietis,* plant to extract ratio = 1:15 - 1:16.3; extractant: Water for injections, isotonised).

Strength 36
605 mg extract of fresh European mistletoe (*Viscum album subsp. abietis,* plant to extract ratio = 1:15 - 1:16.3; extractant: water for injections, isotonised).

Strength 60
1,008 mg extract of fresh European mistletoe (*Viscum album subsp. abietis,* plant to extract ratio = 1:15 - 1:16.3; extractant: water for injections, isotonised).

- The other ingredients are: Sodium chloride, water for injections

What Isorel A (Abietis) looks like and contents of the pack
Isorel A (Abietis) is supplied as 1 ml brown breaking point glass ampoules containing a colourless (strength 1), yellowish (strength 6 to 24) or brownish-yellow (strength 36 and 60), clear isotonic solution for injection.

The following package sizes are available:

- Packs of 10 ampoules à 1 ml

Available in the **strengths 1, 6, 12, 24**, **36** and **60**.

- Packs of 50 ampoules à 1 ml

Available only in **strength 60**.

- Serial packs of 10 ampoules à 1 ml

Containing different strengths in different combinations:

Name of package	contains				
Serial pack I (10 x 1 ml)	2x strength 1	2x strength 6	2x strength 12	2x strength 24	2x strength 36
Serial pack II (10 x 1 ml)	3 x strength 1	3 x strength 6	4 x strength 12		
Serial pack III (10 x 1 ml)	3 x strength 24	3 x strength 36	4 x strength 60		

Not all package sizes may be available in your country.

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder
LUKAS Heil-Betriebsstätte GmbH
Maglern 60
9602 Thörl-Maglern
Austria

Manufacturer
LUKAS Heil-Betriebsstätte GmbH
Maglern 100
9602 Arnoldstein
Austria

MA-number: 17 311

This leaflet was last revised in June 2023.

The following information is intended for healthcare professionals only:

Overdose
Severe localised reactions (redness > 5 cm) may be a sign of an individual overdose. In some cases, symptomatic therapy, e.g. with non-steroidal anti-inflammatory drugs, may be indicated. Fever above 38°C may also indicate that the patient exceeded their tolerated dose.

Temporarily reduce the dose once the symptoms have cleared. If this is not successful, carry out a **desensitization treatment** using the serial packs II and III (see section 3).

If this does not yield any success, either, switch the patient from Isorel A (Abietis) to another Isorel preparation: Isorel P (Pini) or Isorel M (Mali), starting with desensitization treatment.