

LEAFLET: INFORMATION FOR THE PATIENT

Soolantra 10 mg/g cream
ivermectin

Read the entire 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.
- Do you have any further questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms 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.

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1. WHAT IS SOOLANTRA AND WHAT IS IT USED FOR?

Soolantra contains the active substance ivermectin, which belongs to a group of medicines called "avermectins". The cream is used on the skin to treat pimples and spots caused by rosacea (a skin condition of the face).

This medicine is to be used only in adult patients (18 years or older).

2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR BE EXTRA CAREFUL WITH IT?

When should you not use this medicine?

- You are allergic (hypersensitive) to any of the substances in this medicine. You can find these substances in section 6.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

In some patients, the symptoms of rosacea (a skin condition of the face with red spots, bumps, and pimples) may worsen at the start of treatment. However, this is not common and usually disappears within 1 week of treatment. Tell your doctor if this occurs with you.

Are you using any other medicines?

Are you using any other medicines besides Soolantra, or have you done so recently, or is there a possibility that you will use other medicines in the near future? Tell your doctor or pharmacist, as these medicines can affect your treatment with Soolantra or Soolantra can affect your treatment with these medicines.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine. The use of this medicine during pregnancy is not recommended.

If you are breastfeeding, you should not use this medicine. You should have stopped breastfeeding before starting treatment with this medicine. Consult your doctor, he will help in deciding whether to continue treatment with this medicine or breastfeeding, taking into account the benefit of the treatment and the benefit of breastfeeding.

Driving and using machines

This medicine has no or very little influence on the ability to drive and use machines.

Soolantra contains:

- Cetyl alcohol and stearyl alcohol, which can cause local skin reactions (e.g., contact dermatitis).
- Methylparahydroxybenzoate (E218) and propylparahydroxybenzoate (E216), which can cause allergic reactions (possibly delayed).
- Propylene glycol 20 mg per gram of cream.

3. HOW DO YOU USE THIS MEDICINE?

Always use this medicine exactly as your doctor has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Important: This medicine is intended for adults and exclusively for use on the skin of the face. Do not use this medicine on other body parts, especially not on moist areas of the body, such as your eyes, mouth, or mucous membranes (such as the inside of the nose or vagina). Do not swallow.

It is recommended to apply this medicine once daily to the face. A small amount of the cream, the size of a pea, should be applied to the forehead, chin, nose, and each cheek. Then it should be gently and evenly spread in a thin layer over the entire face.

You should avoid the eyelids, lips, and mucous membranes such as the inside of the nose, mouth, and eyes. If some cream accidentally gets in or near the eyes, eyelids, lips, mouth, or mucous membranes, rinse them immediately and thoroughly with water.

Do not apply cosmetics (such as another facial cream or makeup) immediately before applying Soolantra daily. You may use these products only after the applied Soolantra has dried.

After applying this medicine, you should wash your hands immediately.

You should use this medicine daily during the treatment course, and the treatment course may be repeated. Your doctor will tell you how long you need to use this medicine. The duration of treatment varies from person to person and depends on the severity of the condition.

You may notice an improvement after 4 weeks of treatment. If there is no improvement after 3 months, you should stop the treatment with this medicine and consult your doctor.

Liver disorder

If you have a liver disorder, you should consult your doctor before using Soolantra.

Use in children and adolescents under 18 years

Do not use this medicine in children or adolescents under 18 years.

How can the tube with a push-and-twist cap be opened?

To avoid spilling, do not squeeze the tube while opening or closing it.

Push the cap down and turn it counterclockwise (turn to the left). Then remove the cap.

How can the tube with a push-and-twist cap be closed?

Push the cap down and turn it clockwise (turn to the right).

Have you used too much of this medicine?

If you have applied more than the recommended daily dose, contact your doctor; he or she will advise you on what to do.

Have you forgotten to use this medicine?

Do not use a double dose to make up for a forgotten dose.

If you stop using this medicine

Pimples and spots will only be reduced after this medicine has been applied several times. It is therefore important that the use of this medicine is continued for the entire period prescribed by the doctor.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

This medicine can cause the following side effects:

Common (affects less than 1 in 10 people):

- burning sensation of the skin

Uncommon (affects less than 1 in 100 people):

- skin irritation
- itchy skin
- dry skin
- worsening of a skin condition of the face with red spots, bumps, and pimples (rosacea). (Then contact your doctor)

Side effect with unknown frequency (cannot be estimated from the available data):

- redness of the skin

- inflammation of the skin
- swollen face
- elevation of liver enzymes (ALT/AST)

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to any side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. HOW TO STORE THIS MEDICINE?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the label on the packaging after "EXP:". It includes a month and a year. The last day of that month is the expiry date.

After first opening the tube, the product should be used within 6 months.

There are no special storage conditions for this medicine.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

CONTENTS OF THE PACKAGING AND OTHER INFORMATION

What substances are in this medicine?

- The active substance in this medicine is ivermectin. One gram of cream contains 10 mg of ivermectin.
- The other substances in this medicine are: glycerol, isopropyl palmitate, carbomer, dimethicone, disodium edetate, citric acid monohydrate, cetyl alcohol, stearyl alcohol, macrogol cetostearyl ether, sorbitan stearate, methylparahydroxybenzoate (E218), propylparahydroxybenzoate (E216), phenoxyethanol, propylene glycol, oleyl alcohol, sodium hydroxide, purified water.

What does Soolantra look like and what is in a package?

Soolantra is a white to pale yellow cream. It is supplied in tubes containing 30 or 45 grams of cream. The tubes have a press-and-twist cap. Packaging size of 1 tube.

Marketing authorization holder and manufacturer

Marketing Authorization Holder:

Euro Registratie Collectief b.v.

Kempkens 2200

5465 PR Veghel

Repacker (see label on the outer packaging):

Brocef B.V., Marostraat 43, 1060 LG Amsterdam

or

Stephar B.V., Kempkens 2200, 5465 PR Veghel

Manufacturer:
Laboratoires Galderma
Z.I. Montdésir
74540 Alby-sur-Chéran
France

Registered under
RVG 122092//115310 Soolantra 10 mg/g cream (origin: Germany)

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