Package leaflet: Information for the patient

Soolantra 10 mg/g cream
ivermectin

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 Soolantra is and what it is used for
2. What you need to know before you use Soolantra
3. How to use Soolantra
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1. What Soolantra is and what it is used for

Soolantra contains the active substance ivermectin that belongs to a group of medicines called avermectins. The cream is used on the skin to treat pimples and spots found with rosacea.

Soolantra should be used in adults only (18 years of age or older).

2. What you need to know before you use Soolantra

Do not use Soolantra:
- if you are allergic to ivermectin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using Soolantra.

At the start of the treatment, some patients may experience worsening of the symptoms of rosacea, however this is uncommon and usually resolves within 1 week of the treatment. Talk to your doctor if this happens.

Other medicines and Soolantra
Other medicines may have an effect on Soolantra, you should therefore tell your doctor if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding
Soolantra is not recommended during pregnancy.
If you are breast-feeding, you should not use this medicine, alternatively, you should stop breast-feeding before start treatment with Soolantra. You should consult your doctor to help you decide between using Soolantra and breast-feeding, taking into account the benefit of the treatment and the benefit of breast-feeding.

Driving and using machines
Soolantra has no or negligible influence on the ability to drive and use machines.

Soolantra contains:
- **Cetyl alcohol** and **stearyl alcohol** which may cause local skin reactions (e.g. contact dermatitis),
- **Methyl parahydroxybenzoate (E218)** and **propyl parahydroxybenzote (E216)** which may cause allergic reactions (possibly delayed),
- **Propylene glycol** which may cause skin irritation.

3. How to use Soolantra

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

Important: Soolantra is intended for adults and only for use on the skin of the face. Do not use this medicine on other parts of your body, especially not moist body surfaces, e.g. your eyes, your mouth or any mucosa. Do not swallow.

The recommended dose is one application on facial skin per day. Apply a pea size amount of the cream to each of the five areas of the face: forehead, chin, nose and each cheek. Then spread the cream as a thin layer across the entire face.

Make sure to avoid the eyelids, lips and any mucosa such as inside the nose, the mouth and the eyes. If you accidentally get cream in the eyes or near the eyes, eyelids, lips, mouth or mucosa wash the area immediately with plenty of water.

Do not apply cosmetics (such as other facial creams or make-up) before the daily application of Soolantra. These products can be used after the applied cream has dried.

Wash your hands immediately after applying the cream.

You should use Soolantra daily over the treatment course and the treatment course may be repeated. Your doctor will tell you how long you will need to use Soolantra. The duration of treatment can vary from person to person and depends on the severity of the skin disorder.

You may notice an improvement after 4 weeks of treatment. In case of no improvement after 3 months, you should discontinue Soolantra and consult your doctor.

Hepatic impairment
If you have liver problems, please consult your doctor before using Soolantra.

Use in children and adolescents
Soolantra should not be used by children and adolescents.

How to open the tube with child-resistant cap
To avoid spilling, do not squeeze the tube while opening or closing.

Push down on the cap and turn counter clockwise (turn to the left). Then pull the cap off.





How to close the tube with a child-resistant cap
Push down and turn clockwise (turn to the right).



If you use more Soolantra than you should
If you use more than the daily recommended dose, please contact your doctor, who will advise you on what action to take.

If you forget to use Soolantra
Do not use a double dose to make up for a forgotten dose.

If you stop using Soolantra
Pimples and spots will be reduced only after several applications of this medicine. It is important that you continue using Soolantra as long as prescribed by your doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Soolantra may cause the following side effects:

Common side effect (may affect up to 1 in 10 people):
- Burning feeling of the skin

Uncommon side effects (may affect up to 1 in 100 people):
- Irritation of the skin
- Itching of the skin
- Dry skin

- Rosacea aggravation (please consult your doctor)

Not known side effect (frequency cannot be estimated from the available data):
- Redness of the skin
- Inflammation of the skin
- Swelling of the face
- Liver enzyme elevations (ALAT/ASAT)

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 ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

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

5. How to store Soolantra

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 and tube after EXP. The expiry date refers to the last day of that month.
After first opening of the tube, use the product within 6 months.

This medicine does not require any special storage conditions.

Do not throw away unused Soolantra cream 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 Soolantra contains
- The active substance is ivermectin. One gram of cream contains 10 mg of ivermectin.
- The other ingredients are glycerol, isopropyl palmitate, carbomer, dimeticone, disodium edetate, citric acid monohydrate, cetyl alcohol, stearyl alcohol, macrogol cetostearyl ether, sorbitan stearate, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), phenoxyethanol, propylene glycol, oleyl alcohol, sodium hydroxide, purified water.

What Soolantra looks like and contents of the pack
Soolantra is a white to pale yellow cream. It is supplied in tubes containing 2, 15, 30, 45 or 60 grams of cream. The larger tubes have a child resistant closure whilst the 2 g tube does not.
Pack size of 1 tube.
Not all pack sizes may be marketed.

This medicinal product is authorised in the Member States of the EEA under the following name:

Austria, Germany, Portugal :	Soolantra 10 mg/g Creme
Belgium, Luxemburg:	Soolantra 10 mg/g crème Soolantra 10 mg/g Creme
Bulgaria:	Soolantra 10 mg/g Крем
Cyprus, Greece:	Soolantra 10 mg/g Κρέμα
Czech Republic, Hungary, Slovakia :	Soolantra 10 mg/g krém
Denmark	Soolantra
Estonia :	Soolantra 10 mg/g kreem
Finland :	Soolantra 10 mg/g emulsiovoide

France, Netherlands:	Soolantra10 mg/g crème
Iceland, Norway, Poland:	Soolantra 10 mg/g krem
Ireland, United Kingdom:	Soolantra 10 mg/g cream
Italy:	Efacti 10 mg/g crema
Latvia:	Soolantra 10 mg/g krēms
Lithuania:	Soolantra 10 mg/g kremas
Malta:	Soolantra 10 mg/g krema
Romania:	Soolantra 10 mg/g Cremă
Spain :	Soolantra 10 mg/g crema
Sweden :	Soolantra 10 mg/g kräm

Marketing Authorisation Holder and Manufacturer

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