

soolantra® 10 mg/g cream

ivermectin



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
4. Possible side effects
5. How to store Soolantra
6. Contents of the pack and other information

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 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 starting 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.

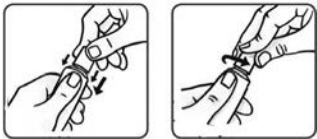
Use in children and adolescents

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.



Galderma Laboratories	Printing Colors
Product code: P26304-8	PMS 432U
Product description: SOOLANTRA CRE 30	
Market: GBR	
Article: Leaflet	
Flat size: 180x315	Font size: 9 pt
Fold size: 180x26,25	Pharmacode: 2638
GRAPHIC DESIGNER: Guillaume ANDRÉ INDUSTRIALIZATION DEPARTMENT LABORATOIRES GALDERMA - Z.I. Galderma - 74540 ALBY-SUR-CHÉRAIN - FRANCE	DIELINES
GALDERMA EST 1981	

