Patient Leaflet According to the Pharmacists' Regulations (Preparations) – 1986

This medicine is sold with a doctor's prescription only

Soolantra®
Cream
1%

Active ingredients:
1 g of cream contains:
Ivermectin 10mg/g

For the list of the additional ingredients, see section 6.
See also 'Important information about some of the medicine's ingredients' in section 2.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think their medical condition is similar to yours.

1. What is the medicine intended for?

Soolantra is indicated in the topical treatment of inflammatory (papulopustular) lesions caused by rosacea in adults.

Therapeutic group: skin preparations.

Soolantra contains the active substance **ivermectin** that belongs to a group of medicines called **avermectins.**

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients the medicine contains (for a list of the other ingredients, see section 6).

Special warnings regarding the use of this medicine:

Consult your doctor or pharmacist before using Soolantra.

If you experienced a severe skin reaction or serious worsening of the rosacea symptoms your doctor may decide to discontinue the treatment with the medicine.
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.

Children and adolescents:
This medicine is not intended for children and adolescents under the age of 18. There is no information on the safety and effectiveness of use of this medicine in children and adolescents under the age of 18.

Drug interactions: If you are taking, or have recently taken, or might use any other medicines, including non-prescription medicines and nutritional supplements, please tell your doctor or pharmacist. Especially inform your doctor or pharmacist if you are taking medicines metabolized in the body through the CYP3A4 mechanism.

Pregnancy, breastfeeding and fertility:
- Soolantra is not recommended during pregnancy, because there is only limited information on the topical use of the medicine in pregnant women.
- Do not use this medicine if you are breastfeeding. If you are breastfeeding, you should stop breastfeeding before starting treatment with Soolantra. You should consult your doctor to help you decide between using Soolantra and breastfeeding, taking into account the benefit of the treatment and the benefit of breastfeeding. It is not known whether Soolantra is secreted into breastmilk after topical administration.
- There is no information on the effect of the medicine on fertility in humans.

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

Important information about some of the medicine's ingredients:
- Cetyl alcohol and stearyl alcohol may cause local skin reactions (e.g. contact dermatitis);
- Methyl parahydroxybenzoate (E218) and propylparahydroxybenzote (E216) may cause allergic reactions (possibly delayed);
- Propylene glycol may cause skin irritation.

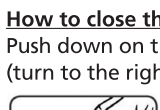
3. How to use this medicine?

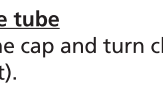
Always use according to the doctor's instructions.
Check with your doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.
Important: Soolantra is intended for adults and only for use on the skin of the face. Do not use this medicine on other parts of your body, especially not moist body surfaces, e.g. your eyes, your mouth or any mucosa. Do not swallow.
The duration of the treatment with the cream, the dosage and the manner of treatment will be determined by the doctor only.
The standard dosage is usually: one application of the cream on facial skin per day.

Liver failure
If you have liver problems, please consult your doctor before using Soolantra.

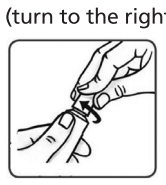
Do not exceed the recommended dose.
Method of administration:
- This medicine is intended for external use only.
- Apply the cream to facial skin once daily. Apply a pea size amount of the cream to each of the five areas of the face: forehead, chin, nose and each cheek.
- Then spread the cream as a thin 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. You can use these products after the medicine has been absorbed.
- After using the cream, wash your hands thoroughly.

How to open the tube? (The tube has a child resistant cap)
To avoid spilling, do not squeeze the tube while opening or closing the cap.
Push down on the cap and turn counterclockwise (turn to the left). Then pull the cap off.





How to close the tube
Push down on the cap and turn clockwise (turn to the right).



Duration of treatment:

Application once daily for a maximum of 4 months.

You must apply Soolantra daily during the treatment. Your doctor will tell you how long you must use the medicine. The duration of the treatment may vary from one person to another and depends on the severity of the skin disorder. You may observe an improvement after four weeks of treatment. If there is no improvement after 3 months of treatment, discontinue the treatment with Soolantra and consult your doctor.
If you have accidentally taken a higher dosage or if a child or another person has accidentally used or swallowed the medicine, go immediately to a doctor or a hospital emergency room and bring the medicine package with you.

If you forgot to use this medicine at the required time, do not apply a double dose to make up for the forgotten dose. Continue with the treatment as recommended by your doctor.

Even if your state of health improves, do not stop the treatment with this medicine without consulting your doctor or pharmacist.

If you stop using the medicine: you may notice an improvement only after several applications. You must continue using Soolantra according to the doctor's instructions.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have further questions concerning the use of the medicine, consult the doctor or pharmacist.

4. Side effects

As for any medicine, the use of Soolantra may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Common side effect (may appear in up to 1 out of 10 users):
- Burning feeling of the skin

Uncommon side effects (appear in 1-10 users out of 1,000):
- Irritation of the skin
- Itching
- Dry skin
- Rosacea aggravation (please consult your doctor)

Side effects of unknown frequency (effects whose frequency has not yet been determined):
- Redness of the skin
- Inflammation of the skin
- Swelling of the face
- Liver enzyme elevations (ALAT/ASAT)

If a side effect appears, if one of the side effects worsens, or you suffer from a side effect not mentioned in the leaflet, consult your doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads to an online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il/

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- After the first opening, the cream may be used within 6 months, but no later than the expiry date marked on the package.
- Storage conditions: store below 30°C.
- Do not throw away unused Soolantra cream via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Additional information

In addition to the active ingredients, the medicine also contains:
Glycerol, Isopropyl palmitate, Cetyl alcohol, Macrogol cetostearyl ether, Stearyl alcohol, Sorbitan stearate, Propylene glycol, Oleyl alcohol, Phenoxyethanol, Dimeticone 20 Cst, Carbomer copolymer type B, Methyl parahydroxybenzoate, Propyl parahydroxybenzoate, Disodium edetate, Citric acid monohydrate, Sodium hydroxide, Purified water.

What does the medicine look like and what does the package contain?
Cream in a plastic tube: 2, 15, 30, 45 or 60 grams.
Not all packs may be marketed.

Registration holder: AMI Technologies, 22 Hanagar St, PO 1522 Hod-Hasharon, 4501317, Israel.

Manufacturer: Laboratories Galderma, Alby-sur-Chéran, France.

Medicine registration number in the National Medicines Registry of the Ministry of Health: 167-59-36606-99

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GALDERMA

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