PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (MEDICINAL PRODUCTS) – 1986

This medicine is dispensed with a doctor's prescription only

SOOLANTRA
Cream
1%

Active ingredients:

Each 1 g of cream contains:

Ivermectin 10 mg/g.

For information on the inactive ingredients and allergens in the medicinal product – see section 6 'Additional information'.

See also 'Important information about some of the ingredients in the medicine' 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 additional questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if seems to you that their medical condition is similar.

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: dermatological 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 hypersensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine (for the list of the inactive ingredients and allergens in the medicinal product – see section 6 'Additional information').

Special warnings regarding the use of the medicine:

Talk to the doctor or pharmacist before using Soolantra.

At the beginning of treatment, some patients may experience worsening of the symptoms of rosacea; however, this is uncommon and usually resolves within 1 week from beginning of treatment. Consult a doctor if this occurs.

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

Children and adolescents:

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

Drug interactions:

If you are taking, or have recently taken, or might use any other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, the doctor or pharmacist should be informed if you are taking strong CYP3A4 inhibitors at the same time as Soolantra.

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 advantage 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 ingredients of the medicine:

- Cetyl alcohol and stearyl alcohol may cause local skin reactions (e.g., contact dermatitis).
- Methyl parahydroxybenzoate and propyl parahydroxybenzoate may cause allergic reactions (possibly delayed).
- Propylene glycol may cause skin irritation.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicinal product according to the doctor's instructions.

Check with the doctor or pharmacist if you are not sure about the dosage and treatment regimen of the medicinal product.

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 on moist body surfaces, e.g., the eyes, the mouth or any other mucosa. Do not swallow.

The dosage and treatment regimen will be determined by the doctor only.

The recommended dose is generally: one application of the cream on facial skin per day.

Hepatic impairment:

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-sized amount of the cream to each of the five areas of the face: forehead, chin, nose and each cheek.
- Then spread the cream by applying a thin layer over the entire face.

- Make sure to avoid contact with the eyelids, lips, and any other 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 any other 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 cream has dried.
- After applying the cream wash your hands immediately.

How to open the tube?

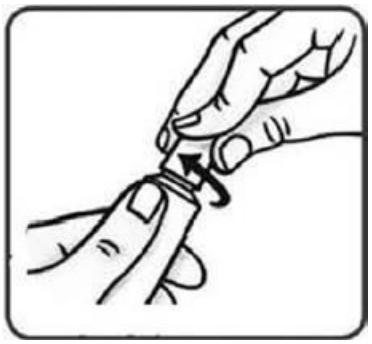
(For packages with a volume of 15, 30, 45 and 60 grams – the tube has a child-resistant cap).

To avoid leakage, do not squeeze the tube while opening or closing the cap.

Push down on the cap and turn counterclockwise (towards the left) and then pull the cap off.

How to close the tube?

Push down on the cap and turn clockwise (towards the right).



Duration of treatment:

Application once daily for a maximum of 4 months.

You should use Soolantra daily during the course of the treatment. The doctor will tell you how long you need to 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, refer to the doctor or a hospital emergency room immediately and bring the medicine package with you.

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

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

If you stop taking the medicine:
The skin lesions will show improvement only after using Solantra several times. It is important to continue using Solantra according to the doctor's instructions**.**

Do not take medicines in the dark! Check the label and the dose <u>each time</u> 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. <u>SIDE EFFECTS</u>

As with 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.
If you experienced significant worsening, with a severe skin reaction, stop using the medicine and consult a doctor about subsequent treatment.

<u>Common side effect, that appears in 1-10 users out of 100</u>:
- Burning feeling of the skin

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

<u>Side effects of unknown frequency (effects whose frequency has not yet been determined)</u>:
- Redness of the skin
- Inflammation of the skin
- Swelling of the face
- Liver enzyme elevation (ALAT/ASAT) / transaminases increased

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 with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (<u>www.health.gov.il</u>) that directs you to the 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 should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- After the first opening, the cream may be used for 6 months, but no later than the expiry date marked on the package.
- Storage conditions: store below 30°C.
- If the cream changes color or there is a change in texture, refer to the pharmacist.
- Do not throw away unused Soolantra cream via wastewater or household waste. Ask your 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 are the contents of the package?

White to light yellow cream in a plastic tube: 2, 15, 30, 45 or 60 grams.

Not all package sizes may be marketed.

Registration holder: A.M.I Medical Technologies Limited, Hanagar 22, Hod-Hasharon, 4501317, Israel.

Manufacturer: Laboratories Galderma, Z.I. Montdesir 74540, 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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