Applicant: Galderma Laboratories South Africa (Pty) Ltd
Product name: Soolantra
Dosage form and strength: Cream-Each gram of cream contains 10 mg of ivermectin.
Registration number: 49/13.12/0906

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

Soolantra 10 mg/g cream

Ivermectin

Read all of this leaflet carefully before you start using **Soolantra** 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, pharmacist, nurse or other health care provider.
- Soolantra has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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 moderate to severe inflammatory pimples and spots found with

rosacea (papulopustular type).

Soolantra should be used in adults 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).
- if you are pregnant or breastfeeding your baby

Warnings and precautions

Take special care with Soolantra**:**

Talk to your doctor or health care provider before using Soolantra.

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

Other medicines and Soolantra

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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

Pregnancy and breastfeeding

You should not use Soolantra if you are pregnant.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using Soolantra.

You should not breastfeed your baby if you are on treatment with Soolantra alternatively, you should stop breastfeeding before you start treatment with Soolantra.

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

Do not share medicines prescribed for you with any other person.

Always use Soolantra 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 Soolantra on other parts of your body, especially not moist body surfaces, e.g. your eyelids, eyes, inside your nose, your mouth or any mucosal surface. Do not swallow. Do not use Soolantra in your eyes, mouth or vagina.

The dose is one application on each of the affected facial skin areas per day at bedtime. Apply a pea size amount of the cream to each of the affected areas of the face (forehead, chin, nose and each cheek), which corresponds to a maximum recommended daily dose of 1 g in total weight. Then spread the cream as a thin layer across the affected areas of the face. The maximal amount of Soolantra cream to use per day is 1 gram (equivalent to 10 mg ivermectin).

Make sure to avoid the eyelids, lips and any mucosal surface 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. If you have the impression that the effect of Soolantra is too strong or too weak, tell your doctor or pharmacist. 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 less than 18 years of age

Soolantra should not be used by children and adolescents less than 18 years of age.

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

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use Soolantra

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

If you stop using Soolantra

Inflammatory pimples and spots will be reduced only after several applications of Soolantra. 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 Soolantra, ask your doctor or pharmacist.

4. Possible side effects

Soolantra can have side effects.

Not all side effects reported for Soolantra are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using Soolantra, please consult your health care provider for advice.

If any of the following happens, stop using Soolantra and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- severe rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to Soolantra. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent (may affect up to 1 in 10 people) side effects:

- Burning feeling of the skin

Less frequent (may affect up to 1 in 100 people) side effects:

- Irritation of the skin
- Itching of the skin
- Dry skin
- Rosacea aggravation (please consult your doctor)

Side effects of unknown frequency:

- Redness of the skin
- Inflammation of the skin
- Swelling of the face
- Liver enzyme elevations ALAT/ASAT (Your doctor will inform you about this finding)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. You can also report side effects directly to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

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

5. How to store Soolantra

Store all medicines out of reach of children.

Store at or 30 °C. This medicine does not require any special storage conditions.

After first opening of the tube, use the product within 6 months.

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.

Do not throw away unused Soolantra cream via wastewater or household waste. Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets). 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 the cream contains 10 mg of ivermectin.

The other ingredients are glycerol, isopropyl palmitate, carbomer, dimeticone, disodium edetate, citric acid monohydrate, cetyl alcohol 3,5 mg/g, stearyl alcohol 2,5 mg/g, macrogol cetostearyl ether, sorbitan stearate, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), phenoxyethanol, propylene glycol, oleyl alcohol 2,0 mg/g, sodium hydroxide (for pH-adjustment), purified water.

What Soolantra looks like and contents of the pack

Soolantra is a white to pale yellow cream.

It is supplied in white plastic tubes containing 2, 15, 30, 45 or 60 grams of cream. The larger tubes have a white plastic child resistant cap whilst the 2 g tube has a white non child resistant plastic cap.

Pack size of 1 tube.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Galderma Laboratories South Africa (Pty) Ltd

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Product name: Soolantra
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Bryanston,

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