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

The medicine is dispensed with a doctor's prescription only

Sunactic 3% Gel

The gel contains Diclofenac Sodium at a concentration of 3%.
1 gram of Sunactic Gel contains 30 mg Diclofenac Sodium.

Inactive ingredients and allergens in the product: see in section 2 "**Important information about some of the ingredients of this medicine**" and section 6 in the leaflet.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further 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 it seems to you that their medical condition is similar.

1. What is the medicine intended for?

Sunactic Gel in intended for topical treatment of actinic keratosis.

Therapeutic group: non-steroidal anti-inflammatories.

2. Before using the medicine

Do not use the medicine if:
- You are hypersensitive (allergic) to the active ingredient diclofenac sodium or to any of the other ingredients contained in the medicine.
- You have previously had an allergic reaction, such as skin rash (hives/nettle-rash), breathing difficulties (wheezing) or allergic rhinitis as a result of taking aspirin or any other non-steroidal anti-inflammatory medicine.
- You are in the last three months of pregnancy.

Special warnings regarding use of the medicine:
The possibility of systemic side effects cannot be excluded if you use Sunactic on large areas of skin and over a prolonged period of time.

Before treatment with Sunactic, inform the doctor if:
- you have, or have had in the past, a gastric ulcer or gastric bleeding.
- you have heart, liver or kidney problems.
- you have any type of bleeding disorder or you bruise very easily.
- Avoid sun exposure, including tanning salons, during the course of treatment with Sunactic. If skin reactions occur, discontinue use of the medicine.
- Do not apply to skin wounds, infected skin or dermatitis.
- Avoid contact of Sunactic Gel with the eyes, the inside of the nose and mouth.
- After applying products containing diclofenac on the skin, you can use a permeable (non-occlusive) bandage. Do not bandage the area tightly and occlusively.

Children and adolescents
Sunactic Gel is not intended for children.

Drug interactions
If you are taking or have recently taken other medicines, including non-prescription medicines and nutrition supplements, tell the doctor or pharmacist.

Pregnancy and breastfeeding
If you are pregnant or may have become pregnant, consult the doctor.
Sunactic can be taken with caution during the first six months of pregnancy, but Sunactic **must not** be used during the last three months of pregnancy.
This medicine has a possible side effect of renal injury in the fetus and low levels of amniotic fluid as of the 20th week of pregnancy. It is recommended to avoid using medicines of the NSAIDs class as of the 20th week of pregnancy and to consult a healthcare professional, if necessary.
If you are breastfeeding, consult the doctor.
Sunactic can be used with caution when breastfeeding, but do not use this medicine on the breasts.
If you are pregnant, trying to become pregnant or breastfeeding, and your doctor has prescribed Sunactic treatment for you, you must not apply this medicine to an area larger than a third of the skin area of your body and do not use it for longer than three weeks.

Driving and using machines
Cutaneous application of topical diclofenac has no influence on the ability to drive and use machines.

Important information about some of the ingredients of this medicine
The medicine contains benzyl alcohol that may cause allergic response or mild local irritation.

3. How should you use the medicine?

Always use the medicine according to the doctor's instructions.
Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine. The dosage and manner of treatment will be determined by your doctor only.
The recommended dosage is usually:
- Sunactic can be used twice a day unless the doctor has instructed you otherwise.
- Before use, pierce the aluminum membrane across the tube opening with the cap.
- Gently release a small amount of gel onto the skin over the area to be treated. The amount of gel needed will vary depending upon the size of the area to be treated. Usually, 0.5 grams of gel (about the size of a pea) will be enough for one area of 5 cm x 5 cm. Do not use more than 8 grams per day.

You may feel a cooling effect in the area when you apply the gel to your skin.

Do not exceed the recommended dose.

Treatment duration
- The recommended period of treatment is 60-90 days. Maximum improvement has been seen with treatment periods closer to 90 days. Complete healing may not occur for up to one month after treatment has stopped.
- Wash your hands after applying the gel, unless your hands are the treated area.

How to use
For external use only.
Do not swallow the gel.

If you accidentally used more Sunactic than you should, remove the excess gel by washing with water.
If a child or someone has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to apply Sunactic Gel at the set time, continue to apply as directed, according to the doctor's instructions.
Do not apply a double dose to make up for a missed application.

Continue with the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with this medicine without consulting the doctor.

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 regarding use of the medicine, consult a doctor or pharmacist.

4. Side effects

As with any medicine, use of Sunactic may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not experience any of them.

Discontinue treatment with Sunactic Gel and refer to a doctor as soon as possible if you suffer from any of the following side effects:
Skin rash (hives/nettle-rash), breathing difficulties (wheezing), swelling of the face, allergic rhinitis. These symptoms may indicate an allergy to Sunactic.

If any of the following common side effects occur to a severe degree or persist for more than a few days, discontinue use of Sunactic and refer to a doctor: itching, rash, skin redness, inflammation, contact dermatitis, pain and blisters.

Additional common side effects that occur in 1-10 out of 100 users:
Irritation or tingling in the treatment area, conjunctivitis, allergy, a painful sensation when touching the skin, pins and needles sensation in the skin, muscle stiffness, dermatitis, eczema, dry skin, swelling, rash (including scales or blisters), peeling of the skin, skin ulcer.

Uncommon side effects that occur in 1-10 out of 1,000 users:
Eye pain, dry/watery eyes, abdominal pain, diarrhea, nausea, hair loss, facial swelling, excessive bleeding or oily skin, a measles-like rash.

Rare side effects that occur in 1-10 out of 10,000 users:
Dermatitis with large blisters.

Very rare side effects that occur in fewer than one out of 10,000 users:
Abdominal bleeding, kidney problems, breathing difficulties (asthma), skin rash caused by infection, skin sensitivity to sunlight.

Temporary hair discoloration at the application site has been reported. This is usually reversed upon stopping treatment.

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

Reporting of side effects:
Side effects can be reported to the Ministry of Health by clicking on the link "Report adverse effects and problems associated with medications" that can be found on home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or by clicking on the following link:
https://sideeffects.health.gov.il
Additionally, side effects can be reported to Perrigo via the following address:
www.perrigo-pharma.co.il

5. How should the medicine be stored?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package and tube. The expiry date refers to the last day of that month.
- Store below 25°C.
- Protect from heat.
- Do not freeze.
- Can be used for 3 months after first opening, but not later than the expiry date.
- Do not discard medicines in the waste bin or wastewater (sink, toilet). Ask the pharmacist how to discard of medicines you no longer use. These measures will help protect the environment.

6. Further information

- **In addition to the active ingredient, this medicine also contains:**
  Purified water, glycerin, polyethylene glycol monomethyl ether, diethylene glycol monoethyl ether, hydroxyethyl cellulose, benzyl alcohol.
- **What the medicine looks like and the contents of the package:** An aluminum tube containing 50 grams of transparent - slightly yellow gel closed with a white plastic screw cap. For multiple use.
- **Registration holder and manufacturer:**
  Perrigo Israel Pharmaceuticals Ltd.,
  P.O.B. 16, Yeruham.
- Revised in June 2021 according to MOH guidelines.
- **Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 150-56-33561

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