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 3% concentration.

1 gram of Sunactic contains 30 mg diclofenac sodium.

Inactive and allergenic ingredients in the medicine: see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information" in the leaflet.

Read the 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 is intended for topical treatment of actinic keratosis.

Therapeutic group: Non-steroidal anti-inflammatory.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient diclofenac sodium or to any of the additional ingredients contained in the medicine.
- you have previously experienced an allergic reaction, such as a skin rash (urticaria), 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 can not be ruled out if you use Sunactic on large areas of the 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 problem 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 with the eyes, the inside of the nose and the mouth; after applying preparations 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 is not intended for use in children.

Drug interactions

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

Pregnancy, breastfeeding and fertility

If you are pregnant or may have become pregnant, consult the doctor. Sunactic can be used 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 from the 20th week of pregnancy. Starting from the 20th week of pregnancy, it is recommended to avoid using NSAID class preparations 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 the medicine on the breasts.

If you are pregnant, trying to become pregnant or are breastfeeding, and your doctor has prescribed treatment with Sunactic 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 operating machinery

Cutaneous application of topical diclofenac has no influence on the ability to drive or operate machinery.

Important information about some of the ingredients of the medicine

This medicine contains benzyl alcohol, which may cause an allergic reaction or mild localized 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 uncertain about the dosage and treatment regimen of the medicine. The dosage and treatment regimen will be determined by the 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 on the tube opening with the cap.
- Gently release a small amount of gel onto the skin in the treated area. 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 cool sensation 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 of close to 90 days. Complete healing may not occur for up to one month after treatment has been discontinued.
- 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 a larger amount of Sunactic than needed, 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 at the scheduled time, continue to apply as usual, according to the doctor's instructions.

Do not apply a double dose to compensate for a forgotten dose.

If you plan to stop treatment with the medicine, discuss the implications with the doctor before stopping.

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

Do not take medicines in the dark! Check the label and dose <u>each time</u> you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Sunactic 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.

Discontinue treatment with Sunactic and refer to a doctor as soon as possible if you are suffering from any of the following side effects:

Skin rash (urticaria), 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 in 100 users:

Irritation or tingling in the treatment area, conjunctivitis, allergy, a painful sensation when touching the skin, sensation of pins and needles 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 in 1,000 users:

Eye pain, dry/watery eyes, abdominal pain, diarrhea, nausea, hair loss, facial swelling, excessive bleeding or oily skin, measles-like rash.

Rare side effects that occur in 1-10 in 10,000 users:

Dermatitis with large blisters.

Very rare side effects that occur in fewer than one in 10,000 users:

Abdominal bleeding, kidney problems, breathing difficulties (asthma), infectious skin rash, skin sensitivity to sunlight.

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

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

Reporting side effects:

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 (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

http://sideeffects.health.gov.il

Additionally, you can report to Padagis via the following address: www.Padagis.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants 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 and tube. The expiry date refers to the last day of that month.
- Store below 25°C.
- Protect from heat.
- Do not freeze.
- After first opening, can be used for 3 months, but no later than the expiry date.
- Do not dispose of medicines via the waste bin or sewage water (sink, toilet). Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

- **In addition to the active ingredient, the 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 that contains 50 grams of a transparent-yellowish gel, closed with a white, plastic screw-cap. For multiple uses.
- **Registration holder and manufacturer:** Padagis Israel Pharmaceuticals Ltd., 1 Rakefet St., Shoham.
- Revised in May 2023 according to MOH guidelines.
- **Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 150-56-33561

30203696