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| File Name | | Salatac_Gel-PIL-ENG-D15-F | | | | |
| Product | | Salat | tac gel | Job No. | SO24000658 | |
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Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - <u>1986</u>

This medicine is dispensed without a doctor's prescription

Salatac Gel

Active ingredients

salicylic acid 12%, lactic acid 4%

Inactive ingredients and allergens in this medicine: See section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

- **Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
- Use this medicine according to the instructions in the dosage section in this leaflet. Consult your pharmacist if you need further information. Consult your doctor if the disease symptoms get worse or do not improve after 12 weeks.

1. What is this medicine intended for?

The medicine is intended for the removal of viral warts, corns, and callous-shaped hardened skin.

The active ingredients cause softening and lysis of the corneous skin of the corn.

Therapeutic group: keratolytic combination of active ingredients.

- Warts and verrucas are small excessive growths of skin caused by a certain virus. Warts often occur on the fingers or on the back of the hands. You can recognise the common wart by the "cauliflower-like" appearance of the wart surface. Verrucas occur only on the sole of the foot. They can be painful, and often look like a small white ring of skin with a black dot in the centre. The virus is very infectious. This means that warts and verrucas can grow and spread, particularly if left untreated. The virus can also be transferred from one person to another.
- **Corns and calluses** are hard, thick pads of skin caused by pressure or friction. They usually occur on the feet due to poorly fitting shoes. They can also occur on the hands.

The active ingredients work by:

- softening the hard skin, making it easier to remove with a pumice stone or emery board;
- they also help kill the virus that causes warts and verrucas.

2. Before using this medicine

Do not use this medicine:

- if you are sensitive (allergic) to the active ingredients (salicylic acid, lactic acid) or to any of the other ingredients in this medicine (see the list of inactive ingredients in section 6).
- on or near your face, armpits, breasts, bottom or genital area.
- on birthmarks, moles, hairy warts or any other spot.
- if you are diabetic or suffer from poor blood circulation to your hands and feet.

Special warnings about using this medicine

- If you are unsure whether you have a wart/verruca/corn/callus that is suitable for treatment with Salatac Gel, ask your doctor or pharmacist before starting treatment.
- Apply the gel **carefully** to the wart, verruca, corn or callus **only**, by squeezing the tube **very gently**:
 - **Avoid** contact of the gel with the surrounding healthy skin, especially on young children's delicate skin, because this may cause irritation. If the gel accidentally touches healthy skin, clean it immediately with a tissue, and if necessary, wash the area.

- Do not apply excessive amounts of gel.
- Avoid contact with the eyes, nose, mouth, wounded skin, cuts and scratches. If the gel accidentally gets into the eyes or mouth, it may cause damage. Rinse the eyes or mouth with plenty of water. If rinsing one eye, avoid entry of washing water into the other eye. Then seek urgent hospital attention.
- **Avoid spillage** of the substance, as this may cause damage to you, your clothing and possessions (see section 4):
 - Do not fold the tube because this may damage it and make it leak.
- The medicine is volatile and highly flammable. Do not use the medicine near flames or ignition sources (e.g. burning cigarettes or anything else that might ignite the medicine). Do not light a cigarette or expose yourself to fire until the preparation has completely dried.
- Avoid inhaling the product. If you inhale a lot of the vapour from the gel, it may make you dizzy. If this happens, inhale plenty of fresh air.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist. This product is not known to affect or to be affected by any other medicines.

Pregnancy and breast-feeding

This medicine can be used during pregnancy and breast-feeding. The medicine ingredients have been in widespread use in this and similar preparations for many years, without reports of problems. However, safety trials have not been conducted.

Driving and using machines

Using this product is not known to affect your ability to drive or use machines.

Important information about some of this medicine's ingredients

This medicine contains about 0.30 alcohol (ethanol) in 1 gram of gel, which is equivalent to the concentration of 31% w/w, and may cause a sensation of burning upon application on damaged skin.

3. How to use this medicine?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine

The recommended dosage is usually once a day consistently, usually in the evening before bedtime, until final cure.

How to use:

How to treat a wart/verruca/corn/callus?

- 1. Remove any adhesive bandage.
- 2. Wash the affected area, soak in warm water for 2-3 minutes.
- 3. Dry the area thoroughly using your own towel.
- 4. Apply 1-2 gel drops directly on the wart. Wait until a film forms over the wart. The film will appear within a short period after the substance has dried. Make sure to avoid contact of the gel with the skin surrounding the wart. There is no need to cover with an adhesive bandage.
- 5. On the following evening, carefully remove the film formed during treatment on the previous evening. Repeat the treatment.
- 6. Once a week before treatment, gently rub the treated area with the emery board provided in the pack or a pumice stone, and then continue with the treatment.

Remember: Use Salatac Gel persistently until complete disappearance of the warts. Removal of warts and verrucae may take up to 12 weeks.

<u>Note</u>: Before opening the tube, hold it upright with the opening facing upwards for 30 seconds. Open the cap, remove the red collar and dispose of it safely. Turn the cap upside down and pierce the tube opening using it. Recap the tube tightly.

Do not exceed the recommended dose.

Attention:

- Do not swallow!
- This medicine is intended for external use only.

If you forget to take the medicine

If you forget to apply this medicine at the scheduled time, do not apply a double dose. Apply the next dose at the usual time.

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

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Salatac Gel may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

- While using the gel, you may feel a slight tingling sensation and/or mild tenderness at the treated area. This sensation is usually temporary, and in rare cases may appear as a temporary blemish on the skin.
- If you mistakenly allow the gel to spread onto and remain in contact with areas of healthy skin (see "Special warnings about using this medicine" in section 2), it may cause irritation.
- Spilling the medicine on clothes, fabrics, jewellery, metal or polished surfaces may damage them permanently.

Stop using this product **and tell** your doctor or pharmacist if you experience unacceptable discomfort or if irritation persists.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (<u>www.health.gov.il</u>) which links to an online form for reporting side effects. You can also use this link: <u>https://sideeffects.health.gov.il</u>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package and label. The expiry date refers to the last day of that month

Storage conditions:

Do not store above 25°C.

Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer need. These measures will help protect the environment.

Caution! Flammable substance, keep it away from fire! See "Special warnings about using this medicine" in section 2.

Close the tube tightly with the cap after use.

6. Additional information

In addition to the active ingredients, this medicine also contains:

Ethyl acetate, ethanol (96%), pyroxylin (contains isopropyl alcohol as a damping solvent), camphor

What the medicine looks like and contents of the pack:

A clear colourless gel.

The medicine is supplied in a tube containing 8 g of gel. The tube has a special applicator nozzle. Each pack also includes an emery board.

Registration holder's name and address: Trupharm Marketing 1985 Ltd., Poleg Industrial Park, P.O.B. 8105, Netanya South Industrial Zone

Manufacturer's name and address: Dermal Laboratories Ltd., Gosmore, Herts, UK

Revised in October 2024.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 053-62-26348

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