

PACKAGE LEAFLET *Information for the user*

Salatac™ Gel

12.0% w/w salicylic acid, 4.0% w/w lactic acid

Read all of this leaflet carefully before you start using this product.

Keep this leaflet. You may need to read it again.

Ask your doctor or pharmacist if you need more information or advice.

In this leaflet:

1. What Salatac Gel is and what it is used for
2. Before you use Salatac Gel
3. How to use Salatac Gel
4. Possible side effects
5. How to store Salatac Gel
6. Further information

1. WHAT SALATAC GEL IS AND WHAT IT IS USED FOR

- Salatac Gel is a treatment for warts, verrucas, corns and calluses.
 - **Warts and verrucas** are small excessive growths of skin caused by a type of virus. Warts often occur on the fingers, or on the back of the hands. You can recognise the common wart by the rough “cauliflower-like” appearance of the 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 and friction. They usually occur on the feet due to poorly fitting shoes. They can also occur on the hands.
- Salatac Gel is suitable for use by **adults, children and the elderly**.
- The **active ingredients** in this product are salicylic acid and lactic acid.
- The active ingredients work by:
 - softening the hard skin growth, 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 YOU USE SALATAC GEL

Do not use Salatac Gel if you are **allergic** (hypersensitive) to salicylic acid, lactic acid or any of the other ingredients of Salatac Gel listed in Section 6.

- Do not use this product anywhere on or near your face, armpits, breasts, bottom or genital (sex) area.
- Do not use it on birthmarks, moles, warts with hairs growing from them, or any other spots.
- Do not use this product if you are diabetic or suffer from poor blood circulation to your hands or feet.

Take special care when using this product:

- If you are unsure whether you have a wart, verruca, corn or 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**:
 - take care **not** to apply the product to surrounding healthy skin, especially on young children's delicate skin, because this may cause irritation;
 - do not apply excessive amounts of gel.
- Keep the product away from your eyes, nose, and mouth, and from broken skin, cuts and grazes.
- **Avoid spillage** as this may cause damage to you, your clothing and your possessions (see Section 4):
 - do not fold the tube because this may damage it and make it leak.
- This product is volatile and highly flammable. Do not use it near flames or ignition sources (eg burning cigarettes or anything else that might ignite it).
- Avoid inhaling the vapour from the gel.

Using other medicines

This product is not known to affect, or to be affected by any other medicines.

Pregnancy and breast-feeding

This product can be used during pregnancy and while breast feeding. The 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 machinery

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

3. HOW TO USE SALATAC GEL

Use it only on warts, verrucas, corns and calluses on sites for which it is recommended.

Before you use this tube of gel for the first time, open it as follows:

- Find a suitable surface, in case of accidental spillage.
- Hold the tube upright, with the cap uppermost and the base resting on a suitable surface.
- Unscrew and remove the combined white nozzle/cap assembly from the tube.
- Remove the red collar and dispose of it safely.
- Keep the tube upright for 30 seconds.
- Then, without squeezing or over-gripping the tube, and with it still held upright and away from your face:
 - replace the white nozzle/cap assembly onto the screw thread of the tube (taking care to avoid "cross-threading");
 - tighten the nozzle/cap assembly firmly to pierce the top of the tube;
 - briefly loosen the cap (to release any slight pressure in the tube) and then retighten.
- Please note that once in place, a small gap will remain between the base of the nozzle/cap and the top of the tube.

To use the gel (adults, children and the elderly):

Follow these steps **once every day**, usually in the evening. Carry on using the gel in this way until the wart, verruca, corn or callus disappears:

- A. Soak the affected area in warm water for 2 to 3 minutes.
- B. Dry the area thoroughly, using your **own towel** if you have a wart or verruca (this will help stop the infection spreading to other people).
- C. Taking care to avoid squeezing the tube, remove the protective cap, leaving the nozzle attached to the tube.

D. **Carefully** apply a thin coating (one or two drops) of the gel to the top of the wart, verruca, corn or callus **only**:

- avoid the gel spreading to the surrounding healthy skin;
- allow the gel to dry for a few minutes to form a small white patch that sticks to the treated area and is water resistant;
- there is no need to cover the treated area with a sticking plaster;
- always replace the protective cap after use.

E. **The next evening**, carefully peel or pick off the white patch of dried gel from the wart, verruca, corn or callus:

- apply fresh gel as described in steps A to D above;
- if removal of the white patch is difficult, carefully re-apply the gel directly over it and leave it to dry. This will thicken the white patch and make it easier to remove.

F. **Once every week**, before applying fresh gel, **gently** rub the wart, verruca, corn or callus with the emery board provided, or a pumice stone:

- if you are treating a wart or verruca, **do not let anyone else use the emery board or pumice stone as the infection may spread to them.**

G. The length of treatment will vary depending on the size and resistance of the wart, verruca, corn or callus:

- some may go in a relatively short time;
- some warts and verrucas can require up to 12 weeks treatment before they disappear;
- it is important that you do not give up on the treatment until the wart, verruca, corn or callus has disappeared (unless irritation occurs, see section 4 below);
- if the wart, verruca, corn or callus has not disappeared after twelve weeks of treatment ask your doctor or pharmacist for advice.

H. At the end of treatment, if the white patch is difficult to remove, you can leave it because it will eventually fall off by itself.

If the gel accidentally gets on to normal skin, wipe it off straight away with a tissue, and, if necessary, wash the area.

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, take care to avoid washing product into the other eye. Then seek urgent hospital attention.

If you inhale a lot of the vapour from the gel it may make you feel light-headed. If this happens, get plenty of fresh air.

If you forget to use Salatac Gel

Do not worry if you occasionally forget to use this product, just carry on using it when you remember.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Salatac Gel can cause side effects although not everybody gets them:

- While the gel is working you may feel a slight tingling sensation and / or some mild tenderness at the treated area. This 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 normal skin (see precautions in section 2), it may cause irritation.

- If you spill the product on your clothes, fabrics, jewellery or metal and polished surfaces it may damage them permanently.
- **Stop using** this product and **tell** your doctor or pharmacist if:
 - you experience unacceptable discomfort or if irritation persists, or;
 - any of the side effects get serious, or you notice any other side effects not mentioned in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SALATAC GEL

- Keep out of the reach and sight of children.
- Do not use Salatac Gel after the expiry date shown at the end of the tube and on the carton. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Always replace the cap tightly after use.
- Store the bottle upright to avoid spillage.
- The product is highly flammable. Keep it away from flames or ignition sources.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION ABOUT SALATAC GEL

What Salatac Gel contains:

The **active ingredients** are salicylic acid (12.0% w/w) and lactic acid (4.0% w/w).

The **other ingredients** are camphor, pyroxylin, ethanol and ethyl acetate.

What Salatac Gel looks like and contents of the pack

The product is a clear colourless gel.

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

Marketing Authorisation holder

Dermal Laboratories (Ireland) Limited, 38 Main Street, Swords, Co Dublin, K67 E0A2.

Manufacturer

JensonR+ (Ireland) Limited, Unit 15, Daingean Hall, N4 Axis Centre, Longford, N39 W6K0, Ireland.

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