

Package leaflet: Information for the patient

Betametason/Salicylsyra Orifarm 0.5 mg/g + 30 mg/g ointment

betamethasone/salicylic acid

Read all of this leaflet carefully before you start using this medicine 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 or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [Invented name] is and what it is used for
2. What you need to know before you use [Invented name]
3. How to use [Invented name]
4. Possible side effects
5. How to store [Invented name]
6. Contents of the pack and other information

1. What [Invented name] is and what it is used for

[Invented name] contains the active substances betamethasone and salicylic acid. Betamethasone reduce inflammation and has effect on allergic and itchy skin diseases. Salicylic acid is a substance that softens the skin.

[Invented name] is used for psoriasis and other dry and scaly skin diseases in adults and children.

2. What you need to know before you use [Invented name]

Do not use [Invented name]

- if you are allergic to betamethasone or salicylic acid or any of the other ingredients of this medicine (listed in section 6).
- for acne vulgaris, rosacea or perioral dermatitis (rash around the mouth).
- for infected skin diseases caused by fungi or bacteria, without treating the infection at the same time.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using [Invented name].

[Invented name] should not be used on the face or on areas where the skin is to skin such as the groin and armpits without a special recommendation on the prescription from your doctor. Do not use in open wounds. Avoid getting [Invented name] in your eyes.

Contact your doctor if your skin also gets red, irritated, warm or tender as it also might be infected, which need to be treated with another medicinal product.

Bandages should be avoided in case of infected eczema.

Contact your doctor if you experience blurred vision or other visual disturbances.

Children and adolescents

In particular, you should avoid using [Invented name] for children for longer than agreed with your doctor. Children are at greater risk of side effects.

Other medicines and [Invented name]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

As there is a risk that the foetus may be affected always consult a doctor *before* using [Invented name] during pregnancy.

Passes into the breast milk, but it is unlikely to affect the breast-feeding child. [Invented name] should not be applied to the chest area if you breast-feed.

Driving and using machines

[Invented name] does not affect your ability to drive or use machines.

3. How to use [Invented name]

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The dose is determined by the doctor and is adjusted individually for you.

Adults and children: Usually a thin layer of [Invented name] is applied twice a day, but often one treatment per day is sufficient.

Once improvement has occurred, treatment intervals may be further apart.

Wash your hands after applying the ointment (unless it is the site to be treated) to avoid getting the ointment in the eyes.

If you use more [Invented name] than you should

If you have used more medicine than you should or if a child accidentally ingested the drug, contact a doctor or hospital for risk assessment and advice on action to be taken.

Excessive, prolonged use can cause your adrenal glands to stop work properly (the adrenal glands are found near the kidneys and produce hormones).

If you forget to use [Invented name]

Do not use a double dose to make up for a forgotten dose. Use the next dose as soon as possible and continue treatment according to the dosing instructions.

If you stop using [Invented name]

Do not interrupt treatment abruptly. As with all strong steroids treatment should be gradually phased out.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The risk of side effects increases with the treatment of large body areas, frequent treatments and treatment for a long time.

Uncommon (may affect up to 1 in 100 people):

Skin thinning (skin atrophy), stretch marks in the skin (striae), infections, skin rash of the facial skin, similar to acne and rosacea, rupture of superficial blood vessels, allergic skin reactions in form of increased skin irritation.

Rare (may affect up to 1 in 1,000 people):

When large body areas are treated, effects on the adrenal glands can occur. It disappears when the treatment is stopped. Increased hair growth, pigment changes.

Not known (frequency cannot be estimated from the available data):

Blurred vision.

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 [the national reporting system listed in Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the tube and carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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

6. Contents of the pack and other information

What [Invented name] contains

- The active substances are betamethasone and salicylic acid.
1 g of ointment contains betamethasone dipropionate corresponding to 0.5 mg betamethasone and 30 mg salicylic acid.
- The other ingredients are liquid paraffin and white soft paraffin.

What [Invented name] looks like and contents of the pack

[Invented name] is a white semi-transparent homogeneous ointment.

[Invented name] is available in tubes containing 30 g, 60 g (2 x 30 g) or 90 g (3 x 30 g).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This leaflet was last revised in

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