

Package leaflet: Information for user

Ovixan 1 mg/g cream

mometasone furoate

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Ovixan is and what it is used for

Ovixan contains the active substance mometasone furoate and it is a corticosteroid for cutaneous use. Corticosteroids for cutaneous use are divided into four classes depending on strength and effect: mild effect, medium effect, strong effect and very strong effect. Mometasone furoate belongs to the class “corticosteroid with strong effect”.

Adults and children above 2 years:

Ovixan has an anti-inflammatory effect and reduces itchiness. Ovixan is used to decrease symptoms in connection with inflammatory skin conditions that can be treated with a corticosteroid, e. g. psoriasis (excluding widespread plaque psoriasis) and some types of dermatitis. It does not cure your skin disease, but it relieves your symptoms.

2. What you need to know before you use Ovixan

Do not use Ovixan

- if you are allergic to mometasone furoate, other corticosteroids or any of the other ingredients of this medicine (listed in section 6).
- for other skin diseases that may become worse, especially rosacea (skin disease in the face), acne, rash around the mouth (dermatitis), skin atrophy, itching in the genitals and around the anus, napkin eczema, bacterial infections such as impetigo, tuberculosis (lung disease), syphilis (sexually contagious disease), viral infections such as mouth sores, shingles, chicken-pox, athlete's foot (red, itching, scaling skin on your feet), or *Candida* infection in the genitals that may cause secretion and itching or other skin diseases.
- if you have recently experienced adverse events after a vaccination (e. g. against influenza).
- on wounds or on ulcerated skin.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Ovixan.

- Inform your doctor if you are pregnant, suspect that you are pregnant, or if you are breastfeeding.
- Inform your doctor at once if you experience irritation or hypersensitivity when using Ovixan.
- As for all strong corticosteroids for topical use, treatment should not be stopped suddenly. If long term treatment is stopped relapse in the form of skin inflammation with intense redness, stinging and burning may occur. This can be prevented by decreasing the treatment gradually e.g. by applying the cream less frequently before stopping the treatment.
- Treatment of psoriasis with this medication may result in skin problems becoming worse (e.g. a pustular form of this disease with many small ulcers on your skin may appear). Your doctor must supervise the development of your problems regularly, since this type of treatment requires careful supervision.
- Ovixan should not be used on damaged skin.
- Do not use the cream on your eyelids. Be careful and avoid getting cream in your eyes.
- Contact your doctor if you experience blurred vision or other visual disturbances.

Other medicines and Ovixan

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

Pregnancy, breast-feeding and fertility

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.

Treatment with Ovixan during pregnancy or breast-feeding may only be started after instructions from your doctor.

If your doctor prescribes use of the cream during pregnancy or breast-feeding you must avoid using large quantities and you must only use the cream during a short period of time. Ovixan should not be applied on the breast or on adjacent skin during breast-feeding.

Ovixan contains propylene glycol (E1520) and cetostearyl alcohol

This medicine contains 250 mg propylene glycol (E1520) in each gram cream. Propylene glycol may cause skin irritation, and cetostearyl alcohol may cause local skin reactions (e. g. contact dermatitis).

3. How to use Ovixan

Ovixan may only be used on the skin.

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

Your doctor should supervise your treatment regularly.

Do not use the cream in your face without prescription by your doctor.

Avoid getting cream in your eyes.

You should not cover the treated area with a compress or bandage if your doctor has not instructed you to do so. This is to decrease the risk of adverse events.

Dosage:

Carefully apply a thin layer of cream on the affected skin once daily. You should only use a small amount of the cream. It is enough to use a fingertip unit (from the fingertip to the first joint on an adult finger) to cover an area corresponding to the size as two adult hands. Never use a larger amount, and do not use it more often than advised by your doctor or pharmacist.

Adults, including elderly:

- Do not use the cream on large areas (more than 20 % of the skin surface) or for a long period of time.

Use in children (2 years of age and over):

- Do not use the cream in children above 2 years without prescription by your doctor.
- Do not use the cream on more than 10 % of the child's skin surface.

Children below 2 years:

Ovixan is not recommended for children below 2 years.

If you use more Ovixan than you should

If you swallow the cream by mistake this should not lead to any side effects.

If you have not followed your doctor's instructions and you have used the cream too often and/or during a long period you should ask your doctor or pharmacist for advice.

If you forget to use Ovixan

If you forget to apply the cream at the time when you should, do it as soon as you remember and then continue as before. Do not use the double amount and do not apply the cream twice in a day to compensate for a forgotten treatment.

If you stop using Ovixan

Do not stop treatment suddenly if you have used the cream for a long time since this can be harmful. The treatment should be gradually decreased according to your doctor's instructions.

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

4. Possible side effects

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

Side effects in children and adults that have been reported during use of corticosteroids for cutaneous use include:

Very rare (may affect up to 1 in 10,000 people):

- Inflammation of the hair follicles
- Itching
- Dilated superficial blood vessels or spider veins
- Burning sensation

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

- Pain or other reactions at the application site
- Secondary infections (an infection that appears during or after treatment of another infection or disease)
- Paresthesia (abnormal or numbing sensation on the skin)
- Blurred vision
- Changes in skin colour
- Skin maceration (softening and bleaching of the skin)
- Miliaria (heat rashes, very itchy rashes)
- Acne-like inflammation in the skin
- Skin thinning
- Irregular spots or lines on the skin

Abnormal growth of hair

- Hypersensitivity to mometasone
- Skin inflammation around the mouth
- Recurrent deep infection in a hair follicle (furunculosis)
- Allergic skin inflammation (allergic contact dermatitis)

- Skin irritation and skin dryness
- Rosacea like skin inflammation in face with redness, swelling and blisters on cheeks and nose
- Nonelevated blue or purplish patches in the skin (ekymosis)

Increased use, treatment of larger skin surfaces, longterm use and treatment with occlusion may increase the risk for side effects.

Corticosteroids may affect the normal hormone production of the body. This is more likely during use of high doses during a longer time period.

Additional side effects in children

In particular children that are treated with corticosteroid creams and ointments may absorb the product through the skin, which can lead to a disease called Cushing's syndrome. This syndrome has many symptoms, among these development of a rounder face and weakness.

Growth in children may be inhibited during longterm use. Your doctor will prevent this risk by prescribing the lowest possible corticosteroid dose for a controlled treatment of your symptoms.

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 Ovixan

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.

No special storage instructions.

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 to protect the environment.

6. Contents of the pack and other information

What Ovixan contains

- The active substance is mometasone furoate. Each gram of Ovixan cream contains 1 mg of mometasone furoate.
- The other ingredients are propylene glycol (E1520), cetostearyl alcohol, coconut oil, stearic acid, macrogol stearate, glycerolmonostearate 40-55, sodium citrate (for pH adjustment), citric acid (for pH adjustment) and purified water.

Please see section 2 "Ovixan contains propylene glycol (E1520) and cetostearyl alcohol".

What Ovixan looks like and contents of the pack

Ovixan 1 mg/g cream is a white, odourless cream in an aluminium laminated plastic tube of polyethylene with a white screw-cap of polypropylene.

Pack sizes:

Tubes containing 15 g, 30 g, 35 g, 70 g, 90 g or 100 g cream.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

To be completed nationally

Manufacturer

Bioglan AB
Borrgatan 31
211 24 Malmö
Sweden

Manufacturer

Lichtenheldt GmbH – Werk I
Industriestraße 7 - 11
23812 Wahlstedt
Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Country	Trade names
Denmark	Ovison 1mg/g creme
Finland	Ovixan 1 mg/g emulsiovoide
Germany	MomeGalen 1 mg/g Creme
Iceland	Ovixan 1 mg/g krem
Italy	Ovixan 1 mg/g crema
Norway	Ovixan 1 mg/g krem
Poland	Ovixan 1 mg/g krem
Sweden	Ovixan 1 mg/g kräm

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Other sources of information

Detailed information on this medicine is available on the website of {name of Member State Agency (link)}