

PACKAGE LEAFLET

Package leaflet: Information for the user

Ovixan 1 mg/g cutaneous solution

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, pharmacist or nurse. 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 6 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

- 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 infections with intense redness, stinging and burning may occur. This can be prevented by decreasing the treatment gradually e.g. by applying the solution 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 solution on your eyelids. Be careful and avoid getting solution 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 solution during pregnancy or breast-feeding you must avoid using large quantities and you must only use the solution during a short period of time. Ovixan should not be applied on the breast or on adjacent skin during breast-feeding.

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

Ovixan contains propylene glycol

Ovixan contains propylene glycol that may cause skin irritation.

3. How to use Ovixan

Ovixan is intended for cutaneous (external) use. Ovixan may only be used on the skin.

Always use this medicine exactly as your doctor or pharmacist 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 solution in your face without prescription by your doctor

Avoid getting solution 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 solution on the affected skin once daily. You should only use a small amount of the solution. The bottle has a dropper that makes it easier to apply the solution. Never use a larger amount, and do not use it more often than advised by your doctor or pharmacist.

Adults, including older people:

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

Use in children (6 years of age and over):

- Do not use the solution in children above 6 years without prescription by your doctor.
- Do not use the solution on more than 10 % of the child's skin surface.

Children below 6 years:

Ovixan is not recommended for children below 6 years.

If you use more Ovixan than you should

If you swallow the solution by mistake this should not lead to any adverse effects.

If you have not followed your doctors instructions and you have used the solution 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 solution 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 solution 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 solution for a long time since this can be harmful. The treatment should be gradually decreased according to your doctors 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
- Increased 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)
- Ulcers in the face
- 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)
- Inflammation (including acne like reactions)
- Skin thinning
- Irregular spots or lines on the skin
- Abnormal growth of hair
- Increased sensitivity
- Dryness

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 solutions, 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 bottle and carton after Exp. The expiry date refers to the last day of that month.

Do not store above 30°C.

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 Ovixan contains

- The active substance is mometasone furoate. Each gram of Ovixan cutaneous solution contains 1 mg of mometasone furoate.
- The other ingredients are: propylene glycol, isopropyl alcohol, hydroxypropylcellulose, sodium dihydrogen phosphate dihydrate, concentrated phosphoric acid (for pH adjustment) and purified water.

See section 2 "Ovixan contains propylene glycol".

What Ovixan looks like and contents of the pack

Ovixan 1 mg/g cutaneous solution is a colourless to slightly yellow low-viscous solution filled in white polyethylene bottles with a dropper and a white screwcap of polyethylene.

Pack-sizes: 30 ml, 100 ml and 2x100 ml.

Not all pack-sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

Laboratorio Reig Jofré S.A.

Gran Capitán 10

Sant Joan Despí

08970 Barcelona

Spain

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

Country	Trade names
Czech Republic	OVIXAN 1 MG/G kožní roztok
Denmark	Ovison 1mg/g Kutanopløsning
Finland	Ovixan 1 mg/g Liuos iholle
Iceland	Ovixan 1 mg/g Húðlausn
Italy	OVISON 1 MG/G SOLUZIONE CUTANEA
Poland	Ovixan 1 mg/g roztwór na skórę
Slovenia	Ovixan 1 mg/g dermalna raztopina
Sweden	Ovixan 1 mg/g Kutan lösning

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