

## 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 Cream is one of a group of medicines called topical corticosteroids. These medicines are put on the surface of the skin to reduce the redness and itchiness caused by certain skin problems. Corticosteroid creams, ointments and other topical preparations come in four different potencies or strengths. These are known as mild, moderately potent, potent or very potent. Healthcare professionals will usually refer to topical corticosteroid potency rather than strength. A potent or strong corticosteroid has a much stronger effect than a mild corticosteroid when using the same amount. The concentration of active ingredient that is sometimes included on product packaging does not indicate potency. Ovixan is classed as a strong corticosteroid. Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

In adults and children, Ovixan is used to reduce redness and itchiness caused by certain skin problems called

psoriasis or dermatitis.

Psoriasis is a skin disease in which itchy, scaly, pink patches develop on the elbows, knees, scalp and other parts of the body. Dermatitis is a condition brought on by the skin reacting to outside agents e.g. detergents, causing the skin to become red and itchy.

#### 2. What you need to know before you use Ovixan

Do not use Ovixan if you have any of the following:

- an allergy (hypersensitivity) to mometasone furoate, any of the other ingredients of this medicine (listed in section 6) or to other similar medicines.
- any other skin problems as it could make them worse especially:
  - rosacea (a skin condition affecting the face)
  - acne
  - skin atrophy (thinning of the skin)
  - dermatitis around the mouth
  - genital itching
  - nappy rash
  - cold sores
  - chickenpox
  - shingles
  - warts
  - ulcerated skin
  - wounds
  - other skin infections

Ask your doctor or pharmacist if you are not sure.

#### Warnings and Precautions

Contact your doctor if your psoriasis gets worse or you get raised bumps filled with pus under your skin. Contact your doctor immediately if you experience blurred vision or other visual disturbances. If your skin becomes irritated or sensitive after using Ovixan, you should stop using it and tell your doctor. If you think that you have developed an infection on your skin while using Ovixan, you should tell your doctor.

Side effects that may happen with inhaled or oral corticosteroids may also occur with corticosteroids used on the skin, especially in infants and children.

If you use more than the correct amount of cream and/or

use it for longer than is recommended, it can affect the levels of certain hormones in the body, particularly in infants and children.

In adults the changes in hormone levels may lead rarely to puffiness or rounding of the face, weakness, tiredness, and dizziness when standing or sitting down.

Do not smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

If there is a worsening of your condition during use consult your prescriber – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment.

If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the cream without consulting your prescriber unless your prescriber has previously advised you to do so. If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.

#### Children

If more than the correct amount of cream is used and/or it is used for longer than is recommended, it can affect the child's hormones. This may lead to:

- Delayed growth and development
- A moon face or rounding of the face

#### Other medicines and Ovixan

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

#### Pregnancy, breast-feeding and fertility

You should tell your doctor if you are pregnant or breast-feeding, before you start using Ovixan.

#### 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

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

#### Use in children

Ovixan is not recommended for children under the age of 2.

#### How much to use

Usually for adults and children aged 2 and above, a thin layer of Ovixan Cream should be gently rubbed into the affected area of skin once a day.

#### Before using Ovixan

You should always follow these instructions when using Ovixan:

- Do not use the cream on your face for more than 5 days.
- Do not apply the cream to children, on any part of their body, for more than 5 days.
- Do not put the cream under your child's nappy, as this makes it easier for the active drug to pass through the skin and possibly cause some unwanted effects.
- You should check with your doctor before covering the treated areas with a bandage or plaster. Treated areas on the face or in children should not be covered with a bandage or plaster.
- You should not use a large amount of cream on large areas of the body for a long time (for example every day for many weeks or months).
- Do not use in or around your eyes, including eye-lids.

#### If you use more Ovixan than you should

If you (or somebody else) accidentally swallow the cream, it should not produce any problems. However, if you are worried, you should see your doctor.

If you use the cream more often than you should, or on large areas of the body, it can affect some of your hormones. In children, this may affect their growth and development.

If you have not used the cream as you were told to do and have used it too often and/or for a long time, you should tell your doctor.

#### If you forget to use Ovixan

If you forget to use your cream at the right time, use it as soon as you remember, then carry on as before.

#### If you stop using Ovixan

If you have been using Ovixan for a long time and your skin problem seems to have got better, you should not suddenly stop using the cream. If you do, you may find that your skin becomes red and you may notice stinging or burning. To avoid this, you should speak to your doctor who will gradually reduce how often you need to use the cream until you stop treatment altogether.

#### 4. Possible side effects

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

A few people may find that they suffer from some of the following side effects after using Ovixan:

- allergic skin reactions
- bacterial and secondary skin infections
- acne
- inflammation and/or infection of the hair follicles
- thinning of the skin
- red marks with associated prickly heat
- loss of skin colour
- burning
- stinging
- itching
- tingling
- excessive hair growth
- softening of the skin and stretch marks
- blurred vision.

Steroid withdrawal reaction:

If used over prolonged periods a withdrawal reaction, which might appear to be different from the previous condition, may occur in some patients during treatment or within days to weeks after stopping treatment, with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

Other side effects that may occur with topical corticosteroids are dry skin, skin irritation, dermatitis,

dermatitis around the mouth, and small dilated blood vessels.

#### 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 Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. 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.

In-use shelf life: Until the expiry date printed on the package.

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*  
Biofrontera Bioscience GmbH  
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