

Package leaflet: Information for the user

MOMETASONE ABR 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, 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.

What is in this leaflet

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

1. What Mometasone ABR is and what it is used for

The active ingredient in the product Mometasone ABR cream is mometasone. It belongs to the group of potent corticosteroids and has anti-inflammatory and anti-allergic effects.

Mometasone ABR cream is used in adults and children to reduce the redness and itchiness in certain skin diseases, such as psoriasis and atopic dermatitis.

2. What you need to know before you use Mometasone ABR

Do not use Mometasone ABR

- if you are allergic to mometasone or any of the other ingredients of this medicine (listed in section 6);
- if you are allergic to other corticosteroids;

- if you suffer from certain skin diseases, such as rosacea (a chronic inflammatory disease presenting with red spots on the skin of the nose, cheeks, forehead, chin), acne, skin inflammation (dermatitis) affecting the skin around the mouth, itching in the region of genitals;
- if you have a skin infection, for example, herpes simplex, herpes zoster, fungal or bacterial (impetigo) infection;
- if you have a skin reaction after vaccination.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Mometasone ABR.

- You need to know that if irritation, itching, increased sensitivity of the skin appear, you should stop applying the product and consult your doctor immediately.
- In the event that the usual manifestations of your condition get worse or new symptoms appear, you should consult your doctor. In these cases, it may refer to development of an infection, in which case the doctor will prescribe appropriate treatment. If the signs of infection persist, your doctor may decide that it is necessary to discontinue the use of Mometasone ABR.
- You need to know that this product
 - should not be applied more than 5 days on the skin of the face
 - should not be used in a great amount, for the treatment of large skin areas or for a prolonged period of time (for example, each day for weeks or months)
 - should not be applied in the eye or in vicinity of the eyes because it may lead to the development of glaucoma (elevated pressure of the aqueous humor which can result in loss of vision)
- If this product is assigned to treat your child, you need to know that it should not be applied more than 5 days, and should not be applied in areas under the baby diapers, thus facilitating its penetration through the skin. In these cases, the risk of side effects is higher.
- A regular medical monitoring is required, since the prolonged use of this medicine, like other medicines of this group, may reduce the therapeutic effect, due to the development of tolerance, may lead to chronification of the disease and reduction of the protective capability of the skin, and to an increase of the the risk of skin infections.

Other medicines and Mometasone ABR

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

There is no evidence of unfavourable interactions with other medicines.

Mometasone ABR with food, drink and alcohol

There are no restrictions.

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.

If you are pregnant, making attempts to get pregnant or breast-feeding, the use of Mometasone ABR requires attention. You should use the medicine if only prescribed by a physician, who will assess the risk for your baby.

Driving and using machines

Mometasone ABR has no influence on the ability to drive and use machines.

Mometasone ABR contains stearyl alcohol

The stearyl alcohol, contained in this medicine, may cause local skin reactions, for example, contact dermatitis (a common form of skin irritation, due to the repeated contact of the skin with a certain substance from the external environment).

3. How to use Mometasone ABR

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

Adults, people over 65 years and children

The product is applied on the affected skin (possibly through a gentle massage) in a thin layer once daily.

You need to know that putting bandages (baby diapers may play the role as well) favours the occurrence of skin infections; therefore, these should be used by exception.

This medicine should not be used longer than 5 days in children or if you have to apply it on the skin of the face.

The duration of treatment will be determined by your doctor, but this medicine should not be used every day for weeks or months.

After applying the cream to the affected skin areas, you should not touch your eyes to avoid possible entering of even small amounts of the cream in the eyes. After applying the medicine, wash your hands thoroughly.

If you use more Mometasone ABR than you should

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

If you put a larger dose than the prescribed, you can remove the unnecessary amount of the cream with a tissue and rinse the skin with lukewarm water. If you accidentally swallow (applies especially to children) the contents of the tube, contact your doctor immediately.

Do not use this medicine more often or for a longer period than the specified by the doctor, since in these cases, overdose may develop and certain side effects may occur.

If you forget to use Mometasone ABR

Do not apply a double dose to make up for a forgotten dose. Apply the required amount of the cream as soon as you remember. If it is almost the time for your next dose, continue in accordance to your regular scheme.

If you stop using Mometasone ABR

The time and manner of discontinuation of the treatment will be determined by your doctor. Do not stop the application of the medicine abruptly, and if your doctor has not told you to do this. This particularly applies to the cases of continuous treatment.

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 frequency of the reported side effects is as follows:

Common - affects more than 1 in 100 and less than 1 in 10 users.

Uncommon - affects more than 1 in 1,000 and less than 1 in 100 users.

Rare – affects more than 1 in 10,000 and less than 1 in 1,000 users.

Very rare - affects less than 1 in 10,000 users.

Not known – cannot be estimated from the available data.

The following side effects may occur during the treatment with Mometasone ABR:

Uncommon: dryness, irritation, inflammation of the skin, especially around the lips, softening of the skin.

Very rare: inflammation and infection of the hair roots (folliculitis), burning at the administration site, itching.

Not known: skin infections and inflammations, pustules on the skin (furunculosis), tingling of the skin, thinning and discolouration of the skin, striations, especially with the use of occlusive dressings and application in the field of skin folds, excessive hair growth, pain and other reactions at the administration site.

When using the product for a longer time and on large skin areas, increased absorption through the skin may occur in amounts, which may lead to swelling of the face (the so-called moon face), neck and chest, weight gain and in children, to growth and development retardation. These side effects are more common in children.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. How to store Mometasone ABR

Store below 25°C.

Do not freeze.

After first opening of the pack, store in the original package away from direct sunlight, at a temperature below 25°C.

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 carton after „EXP”. The expiry date refers to the last day of that month.

After first opening of the pack, you can use this medicine for 90 days.

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 Mometasone ABR contains

- The active substance in 1 g cream is mometasone furoate of 1 mg.
- The other ingredients (excipients) are hexylene glycol, purified water, beeswax, white propylene glycol monopalmitostearate, stearyl alcohol, cetareth 20, titanium dioxide, aluminum starch octenylsuccinate, paraffin, white soft, phosphoric acid.

What Mometasone ABR looks like and contents of the pack

Cream.

Mometasone ABR cream is a white to off-white homogenous creamy mass, without air bubbles.

Mometasone ABR 1 mg/g cream of 15 g or 30 g in membrane, lacquered aluminum tubes, closed with a plastic screw cap.

One tube with a patient information leaflet is inserted in a carton.

Marketing Authorisation Holder

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