

Elisone 0.1%

Mometasone furoate
Skin Cream

Composition: Each 1 gm of **Elisone** contains:
Mometasone furoate 1 mg

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What **Elisone** is and what it is used for
2. Before you take **Elisone**
3. How to use **Elisone**
4. Possible side effects
5. How to store **Elisone**
6. Further information

1. What **Elisone** is and what it is used for:

Elisone is one of a group of medicines called topical corticosteroids. It is classified as a "potent corticosteroid".

In adults and children, these medicines are put on the surface of the skin to reduce the redness and itchy 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. Before you use **Elisone**.

Do not use **Elisone**:

- If you are allergic (hypersensitive) to mometasone furoate, any of the other ingredients of **Elisone**, or to similar medicines.

- On 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 **Elisone**, you should stop using it and tell your doctor.

If you think that you have developed an infection on your skin while using **Elisone**, 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 ointment without consulting your prescriber unless your prescriber has previously advised you to 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 **Elisone**

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 **Elisone**.

3. How to use **Elisone**.

Always use **Elisone** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Use in children

Elisone 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 **Elisone** Cream should be gently rubbed into the affected area of skin once a day.

You should always follow these instructions when using **Elisone**:

- 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 **Elisone** 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 **Elisone**

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 **Elisone**

If you have been using **Elisone** 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 as he will gradually reduce how often you need to use the cream until you stop treatment altogether.

4. Possible side effects

Like all medicines, **Elisone** 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 **Elisone**: 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 in addition to vision blurred.

Steroid withdrawal reaction: If used continuously for prolonged periods a withdrawal reaction may occur on 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

To reports any side effect(s):

Jordan:

- Jordan food & Drug administration:
- Tel: 06-5632000
- Website: www.jfda.jo
- Smart application phones: Jordan fda
- Or by fill the side effects on the yellow card.

UAE

- Pharmacovigilance & Medical Device section
- P.O. Box: 1853
- Tel: 800111111
- Email: pv@mh.gov.ae
- Drug Department
- Ministry of Health & Prevention
- Dubai

Saudi Arabia

The National Pharmacovigilance Centre (NPC):

- SFDA Call Center: 19999
- Website: www.sfda.gov.sa
- Email: npc.drug@sfda.gov.sa
- Website: https://ade.sfda.gov.sa/

Oman

Department of pharmacovigilance & drug information

- Drug Safety Center
- Ministry of health, Sultanate of Oman
- Phone No: 22357686 / 22357687
- Fax: 22358489
- Email: pharma-vigil@moh.gov.om
- Website: www.moh.gov.om



for other GNC country :
Please contact the relevant competent authority

5. How to store **Elisone**.

- Keep out of the reach of children.
- Store up to 25°C.

6. Further information.

The active ingredient in **Elisone** is: Mometasone furoate.

Other ingredients are: Mineral Oil, Labralil 2130, Tween 80, Span 80, Glycerol monostearate, White Soft Paraffin, Methyl Paraben, Propyl Paraben, Propylene Glycol, Cetearyl alcohol & Ceteareth 20, Disodium Hydrogen Phosphate Anhydrous, Citric acid anhydrous, Highly purified Water.

Presentation: 15 gm and 30 gm in Aluminium tube.

Produced and marketed by:
Amman Pharmaceutical Industries
King Abdullah II Industrial City State - Sahab
Amman, Jordan

THIS IS A MEDICATION

Medication is a product which affects your health, and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of pharmacist who sold the medication.

The doctor and the pharmacist are experts in medicine, its benefits and risks.

Do not by yourself interrupt the period of treatment prescribed for you.

Do not repeat same prescription without consulting your doctor.

Keep medication out of reach of children.

Concil of Arab Health Ministers
Union of Arab Pharmacists

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