

 جمجوم فارما Jamjoom Pharma	<i>Jamjoom Pharmaceuticals Company</i> <i>Jeddah, Kingdom of Saudi Arabia</i>
Product: <i>Elica Cream 30g</i>	<i>REGIONAL ADMINISTRATIVE</i> <i>INFORMATION</i>

1.3.3.2 English Leaflet

Enclosed



Elica™ 0.1% W/W Cream

Mometasone Furoate

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 Elica™ is and what it is used for
2. Before you use Elica™
3. How to use Elica™
4. Possible side effects
5. How to store Elica™
6. Further information

1. What Elica™ is and what it is used for

Elica™ Cream is one of a group of medicines called topical corticosteroids. It is classified as a “potent corticosteroid”. These medicines are put on the surface of the skin to reduce the redness and itchiness caused by certain skin problems.

In adults and children, Elica™ Cream 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. Before you use Elica™

Do not use Elica™

- if you are allergic (hypersensitive) to mometasone furoate, any of the other ingredients of Elica™, or to other similar medicines.
 - on any other skin problems as it could make them worse especially:
 - rosacea (a skin condition affecting the face).
 - acne.
 - dermatitis around the mouth.
 - genital itching.
 - cold sores.
 - shingles.
 - ulcerated skin.
 - skin atrophy (thinning of the skin).
 - nappy rash.
 - chickenpox.
 - warts.
 - wounds.
 - other skin infections.
- Ask your doctor or pharmacist if you are not sure.

Take special care with Elica™

- if your skin becomes irritated or sensitive after using Elica™, you should stop using it and tell your doctor.

Pregnancy and breast-feeding

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

Important information about some of the ingredients of Elica™ Cream

Elica™ Cream contains cetostearyl alcohol, which can cause local skin reactions (e.g. contact dermatitis), chlorocresol and propylene glycol which can cause skin irritation.

3. How to use Elica™

Always use Elica™ exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Elica™ is not recommended for children under the age of 2. Usually for adults and children, a thin layer of Elica™ Cream should be gently rubbed into the affected area of skin once a day.

You should always follow these instructions when using Elica™:

- 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 Elica™ than you should

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 swallow Elica™

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

If you forget to use Elica™

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 Elica™

If you have been using Elica™ 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, Elica™ 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 Elica™ :
- 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.

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.

5. How to store Elica™

- Keep out of the reach and sight of children.
- Do not store above 30 °C.
- Do not use Elica™ after the expiry date which is stamped on the pack and tube.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Elica™ contains

- The active substance is mometasone furoate 0.1 % w/w.
- The other ingredients are cetomacrogol 1000, cetostearyl alcohol, chlorocresol, white petroleum jelly, liquid paraffin, propylene glycol, sodium dihydrogen phosphate, phosphoric acid 1M, sodium hydroxide 1N and purified water.

What Elica™ looks like and contents of the pack

Elica™ Cream is a white to off white homogenous smooth cream. Elica™ Cream comes in aluminium collapsible tube of 30g.

Marketing Authorisation Holder and Manufacturer

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To report any side effect(s):

• Saudi Arabia:

- The National Pharmacovigilance and Drug Safety Centre (NPC)
- o Fax: +966-11-205-7662
- o Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
- o Toll free phone: 8002490000
- o E-mail: npc.drug@sfda.gov.sa
- o Website: www.sfda.gov.sa/npc

• Other GCC States:

- Please contact the relevant competent authority.

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THIS IS A MEDICAMENT

- Medicament is a product that 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 the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of the reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists



Elica™ Cream is a quality product manufactured by:



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