# **Elicasal<sup>™</sup> Ointment**

# mometasone furoate 0.1% w/w, salicylic acid 5% w/w

# Read all of this leaflet carefully before you start using this

- · 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
- 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

#### In this leaflet:

- 1. What  $Elicasal^{TM}$  ointment is and what it is used for.
- 2. Before you use Elicasal™ ointment.
- 3. How to use Elicasal™ ointment.
- 4. Possible side effects.
- 5. How to store Elicasal™ ointment.
- 6. Further information.

# 1. What $\mathbf{Elicasal}^{^{\mathsf{TM}}}$ ointment is and what it is used

Elicasal™ ointment contains two active ingredients, mometasone furoate and salicylic acid. Mometasone furoate belongs to a group of medicines called topical corticosteroids. It is classified as a "Medium high potent corticosteroid". These medicines are put on the surface of the skin to reduce the redness and itchiness caused by certain skin problems. Salicylic acid softens the top layer of scales on the surface of the skin, which are caused by your skin problem. This allows the mometasone furoate to reach the diseased skin underneath to help heal it.

In adults and children,  $\operatorname{Elicasal}^{\scriptscriptstyle\mathsf{TM}}$  ointment is used to treat skin conditions where the outer surface of the skin is covered by a layer of scales. Your ointment will remove the layer of scales and reduce the redness and itchiness caused by your skin problem.

## 2. Before you use Elicasal™ ointment

## Do not use Elicasal™ ointment

- · if you are allergic (hypersensitive) to mometasone furgate. salicylic acid or any of the other ingredients in Elicasal™ ointment. Please refer to section 6 for list of ingredients.
- · on any other skin problem as it could make it worse especially rosacea (a skin condition affecting the face), acne, dermatitis (skin inflammation) around the mouth, genital itching, nappy rash, cold sores, chickenpox or other skin conditions.
- · on shingles, warts, ulcerated skin, wounds.

# Pregnancy and breast-feeding

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

# 3. How to use Elicasal™ ointment

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

Usually for adults and children, a thin layer of Elicasal™ ointment should be gently rubbed on the affected area of skin twice a day. Not recommended for children under the age of 2 years

## You should always follow these instructions when using Elicasal<sup>TM</sup> ointment:

- · Do not use a large amount of ointment on large areas of the body for a long time (for example every day for many weeks or months) unless your doctor advice.
- · Avoid getting the ointment in your eyes.
- Do not use the ointment on your face for more than 5 days
- · Do not apply the ointment to children, on any part of their body, for more than 5 days.
- · Do not put the ointment 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

# If you use more $\mathbf{Elicasal}^{\mathsf{TM}}$ ointment than you should

If you use the ointment more often than you should, or on large areas of your body, it can affect some of your hormones. In children this may affect their growth and development. It also may cause you to feel and/or be sick and to hear ringing in your ears. If you have not used the ointment 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 Elicasal™

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

#### If you forget to use Elicasal™ ointment

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

If you have any further questions on the use of this product, ask your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, Elicasal™ ointment 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 Elicasal<sup>17</sup>

- Thinning of the skin, stinging, blistering, peeling, swelling, itching, burning, skin rash, dryness of the skin and you may notice red marks. This can happen more easily in infants and children.
- Inflammation of the hair follicles, excessive hair growth, reduced skin pigmentation and allergic skin reactions.
- Dermatitis (skin inflammation), a condition brought on by the skin reacting to outside agent e.g. detergents, causing the skin to become red and itchy

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

#### 5. How to store Elicasal™ ointment

Keep out of the reach and sight of children.

Do not store above 30 °C.

Do not use Elicasal<sup>™</sup> after the expiry date which is stamped on the pack and tube.

Advice to be used within 3 months of tube opening

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 Elicasal™ ointment contains:

Each gram contains the active substances:

Mometasone furoate 1 mg and salicylic acid 50 mg. The other ingredient is white petroleum jelly

What Elicasal™ ointment looks like and contents of the pack

Elicasal™ ointment is an off white homogenous smooth ointment, free from grit or lumps.

Elicasal<sup>™</sup> ointment comes in aluminium collapsible tube of 30g

## Marketing Authorisation Holder and Manufacturer

Jamjoom Pharmaceuticals Co., Jeddah, Saudi Arabia Tel: +966-12-6081111, Fax: +966-12-6081222.

Website: www.jamjoompharma.com

# To report any side effect(s):

Saudi Arabia:

The National Pharmacovigilance and Drug Safety Centre (NPC) Fax: +966-11-205-7662

Call NPC at +966-11-2038222

Exts: 2317-2356-2353-2354-2334-2340.

Toll free phone: 8002490000

E-mail: npc.drug@sfda.gov.sa

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
- 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



Elicasal<sup>™</sup> Ointment is a quality product manufactured by:



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