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| <b>ELICA CREAM</b><br><b>ELICA OINTMENT</b><br><b>ELICA LOTION</b> | <b>PATIENT INFORMATION LEAFLET</b><br><b>Date of Revision: 28 June 2023</b> |
| <b>Organon South Africa (Pty) Ltd</b>                              |                                                                             |

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

S4

ELICA® CREAM

ELICA® OINTMENT

ELICA® LOTION

Mometasone furoate (micronised) 1 mg

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ELICA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### What is in this leaflet

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

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## 1. What ELICA is and what it is used for

- ELICA contains a cortisone-type medicine which is used on the skin to reduce redness and itchiness caused by certain skin problems.
- ELICA is used to treat skin problems, including dermatoses and psoriasis.
- Dermatoses is a non-inflammatory skin disorder, which may cause thickening and hardening of the skin. Psoriasis is a skin disease in which itchy, scaly, pink patches develop on the elbows, knees, scalp and other parts of the body.

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

### Do not use ELICA:

- if you are allergic (hypersensitive) to mometasone or any of the other ingredients of ELICA.
- If you are under the treatment of herpes infections, vaccine reactions or chicken pox (varicella).

## Warnings and precautions

### Take special care with ELICA:

- ELICA is for use only on the skin. Avoid contact with the eyes. Use with particular caution on facial skin and only for short periods.
- Do not use ELICA more often or for a longer time than your doctor recommends.
- Do not use ELICA if your skin condition worsens. Check with your doctor if your skin condition worsens.
- Do not use ELICA on large areas of the body, as this will increase the amount absorbed.
- Do not use ELICA under bandages and plasters or if skin is damaged.
- Do not use ELICA in any skin crease areas.

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- Children and adolescents who must use ELICA should be followed closely by their doctor, since ELICA is absorbed through the skin and can affect growth or cause other unwanted effects.
- ELICA should not be used in nappy areas and ideally should not be used in infants and young children at all.

If you experience blurred vision or visual disturbances, contact your doctor.

If there is a worsening of your condition during use consult your doctor – 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 doctor unless your doctor 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.

### **Other medicines and ELICA**

Always tell your healthcare provider if you are taking any other medicine (this includes all complementary or traditional medicines).

### **Pregnancy and breastfeeding**

ELICA should not be used in pregnancy and in mothers who are breastfeeding.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using this medicine.

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### 3. How to use ELICA

- Do not share medicine prescribed to you with any other person.
- Always use ELICA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
- ELICA is not recommended for children under the age of 2 years old.
- Apply a thin film of ELICA Cream or Ointment to cover the affected area and massage in gently, usually once a day, or as directed by your doctor.
- Apply a few drops of ELICA Lotion to the affected skin area and massaged gently and thoroughly into the skin once daily.

If you have an impression that the effect of ELICA is too strong or too weak, tell your doctor or pharmacist.

#### **If you use more ELICA than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre.

#### **If you forget to use ELICA**

If you forget to use your cream, ointment or lotion at the right time, use it again at your next dose as usual.

Do not use a double dose to make up for forgotten individual doses.

#### **If you stop using ELICA**

If you stop using ELICA, you will lose the effects of this medicine. You should not stop using this medicine, unless your doctor tells you as your symptoms may return.

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#### 4. Possible side effects

ELICA can have side effects.

The following have been reported and the frequencies are unknown: Burning, itching, irritated or dry skin, irritation or redness of the face, increased hair growth, blurred vision, acne, change in skin colour, thinning of skin with easy bruising, stretch marks or other signs of irritation not present before use of ELICA.

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.

Not all side effects reported for ELICA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using ELICA, please consult your healthcare provider for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

#### Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide

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more information on the safety of ELICA.

## 5. How to store ELICA

ELICA Cream and Ointment: Store at or below 25 °C. Protect from light.

ELICA Lotion: Store at or below 30 °C. Protect from light.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the tube or bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

## 6. Contents of the pack and other information

### What ELICA contains

The active substance is mometasone furoate (micronised).

ELICA CREAM: The other ingredients are: hexylene glycol, hydrogenated soybean lecithin, phosphoric acid, titanium dioxide, starch octenylsuccinate, white wax, white soft paraffin and purified water.

ELICA Ointment: The other ingredients are: Hexylene glycol, phosphoric acid, propylene glycol stearate, white beeswax, white soft paraffin and purified water.

ELICA Lotion: The other ingredients are: Hydroxypropylcellulose, isopropyl alcohol, monobasic sodium phosphate, phosphoric acid, propylene glycol and purified water.

### What ELICA looks like and contents of the pack

ELICA Cream: A smooth, white to off-white cream.

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ELICA Ointment: A smooth, white to off-white, opaque ointment.

ELICA Lotion: A colourless to light yellow, smooth lotion.

ELICA Cream: Tubes of 10 g, 15 g, 20 g, 30 g and 45 g.

ELICA Ointment: Tubes of 10 g, 15 g, 20 g, 30 g and 45 g.

ELICA Lotion: White, plastic bottles of 20 mL, 30 mL and 100 mL.

### **Holder of Certificate of Registration**

Organon South Africa (Pty) Ltd

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### **This leaflet was last revised on**

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### **Registration numbers**

ELICA Cream: 31/13.4.1/0544

ELICA Ointment: 31/13.4.1/0545

ELICA Lotion: 31/13.4.1/0590

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