1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ASPEN MOMETASONE CREAM 1,0 mg/1,0 g

Mometasone furoate

Read all of this leaflet carefully before you start using ASPEN MOMETASONE CREAM

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

1. What ASPEN MOMETASONE CREAM is and what it is used for

ASPEN MOMETASONE CREAM belongs to a group of medicines called topical corticosteroids and is used to reduce the redness and swelling caused by skin problems such as psoriasis and corticosteroid-responsive dermatoses.

2. What you need to know before you use ASPEN MOMETASONE CREAM

Do not use ASPEN MOMETASONE CREAM:

- If you are hypersensitive (allergic) to mometasone or any of the other ingredients of ASPEN MOMETASONE CREAM (listed in section 6).
- If you have a virus that causes contagious sores, most often around the mouth or on the genitals (*herpes simplex, vaccinia or varicella*).
- If you have any untreated fungal infections.

Warnings and precautions

Special care should be taken with ASPEN MOMETASONE CREAM:

- If irritation or sensitisation occur with the use of ASPEN MOMETASONE CREAM, you should stop using this medicine and tell your doctor.
- If you have a history of Cushing's syndrome, high blood sugar (hyperglycaemia), and excess sugar in urine (glucosuria).
- During long term or inappropriate use on large areas of damaged skin and in flexures.
- If treatment is suddenly discontinued.
- If you are applying this medicine near the eyes.
- If your condition has resolved and you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using this medicine

without consulting your doctor. On recurrence the redness extends beyond the initial treatment area and you may experience a burning sensation.

- Use of this medicine can change the appearance of some lesions, delay healing and make establishing a diagnosis difficult for your doctor.
- If used for the treatment of psoriasis, as it may make the condition worse and the pustular form of the disease may be provoked. Your doctor will want to see you more often.
- If you have an infection of the skin this will need to be treated.
- If your vision becomes blurred or you experience other visual disturbances.
- If you smoke or go near naked flames you may experience severe burns.

Children and adolescents

- There is no experience with ASPEN MOMETASONE CREAM in children for more than three weeks of use.
- Use in children under the age of two years is not recommended.

Other medicines and ASPEN MOMETASONE CREAM

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

Pregnancy, breastfeeding and fertility

You should not use ASPEN MOMETASONE CREAM if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, 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.

Driving and using machines

ASPEN MOMETASONE CREAM is not expected to influence your ability to drive or operate machinery. However, you should not drive, use machinery or perform any tasks that require concentration until you are certain that ASPEN MOMETASONE CREAM does not adversely affect your ability to do so safely (see section 4).

It is not always possible to predict to what extent ASPEN MOMETASONE CREAM may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which ASPEN MOMETASONE CREAM affects you (see section 4).

3. How to use ASPEN MOMETASONE CREAM

Do not share medicines prescribed for you with any other person.

Always use ASPEN MOMETASONE CREAM exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

A thin film of ASPEN MOMETASONE CREAM should be applied to completely cover the whole affected area once daily.

Your doctor will tell you how long your treatment with ASPEN MOMETASONE CREAM will last, however, do not continue for longer than three weeks without your condition being reviewed. Treatment should be discontinued once the condition is under control. If you have the impression that the effect of ASPEN MOMETASONE CREAM is too strong or too weak, tell your doctor or pharmacist.

If you use more ASPEN MOMETASONE CREAM 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 ASPEN MOMETASONE CREAM

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

If you stop using ASPEN MOMETASONE CREAM

You may experience withdrawal reactions such as redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules.

4. Possible side effects

ASPEN MOMETASONE CREAM can have side effects.

Not all side effects reported for ASPEN MOMETASONE CREAM are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using ASPEN MOMETASONE, please consult your healthcare provider for advice.

If any of the following happens, stop using ASPEN MOMETASONE CREAM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ASPEN MOMETASONE CREAM. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Headache, ringing of the ears, vision problems and shoulder pain (benign intracranial hypertension),
- moon like face, unusual rapid weight gain around the belly (Cushingoid state),
- delayed growth (growth retardation),
- a worsened recurrence of your condition shortly after stopping treatment, which causes the skin to burn, sting, itch, peel and/or have oozing pustules (withdrawal syndrome reactions).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Burning sensation,
- allergic contact dermatitis, burning, dryness, small red bumps (folliculitis), irritation, itching (pruritus), secondary infection, skin thinning (atrophy), acneiform eruptions, perioral dermatitis, excessive hair growth over the body (hypertrichosis),
- patches of skin that are lighter than surrounding skin (hypopigmentation), heat rash (miliaria), skin that feels soft, wet or soggy to the touch (maceration), loss of skin

elasticity, dilation of superficial blood vessels, spider veins (telangiectasia), discoloration of the skin resulting from bleeding underneath (ecchymosis).

Side effects with an unknown frequency:

- Infection, painful red bumps under the skin (furuncle),
- abnormal sensation of the skin (paraesthesia),
- vision blurred,
- application site pain, application site reactions.

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, pharmacist or nurse. You can also report side effects to **SAHPRA:** via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/+27 (0)11 239-6200

By reporting side effects, you can help provide more information on the safety of ASPEN MOMETASONE CREAM.

5. How to store ASPEN MOMETASONE CREAM

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep well closed.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 ASPEN MOMETASONE CREAM contains

The active substance is 1,0 mg of mometasone furoate in every 1,0 g of cream. The other ingredients aluminium starch octenylsuccinate, beeswax white, cetearth-20 and stearyl alcohol, hexylene glycol, phosphoric acid (for pH adjustment), propylene glycol stearate, purified water, titanium dioxide (C.I. 77891), white soft paraffin.

What ASPEN MOMETASONE CREAM looks like and contents of the pack

ASPEN MOMETASONE CREAM is a stiff white to off-white oleaginous cream.

ASPEN MOMETASONE CREAM 20 g or 50 g are packed in an aluminium collapsible tube sealed with a white self-piercing, high density polyethylene cap and placed in a unit cardboard carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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