

Applicant: Pharmacare Ltd
Product name: MACEPATAN FATTY OINTMENT
Dosage form and strength: Each 1 g contains 1 mg of methylprednisolone aceponate

MODULE 1
1.3.2.1

1.3.2.1 Patient Information Leaflet

SCHEDULING STATUS

S4

MACEPATAN FATTY OINTMENT 1 mg/g

Methylprednisolone aceponate

Read all of this leaflet carefully before you start using MACEPATAN FATTY OINTMENT

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

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1. What MACEPATAN FATTY OINTMENT is and what it is used for

MACEPATAN FATTY OINTMENT belongs to a group of medicines called topical corticosteroids and is used to treat a variety of eczemas, which are skin conditions that cause dry, sensitive, red, swollen (inflamed), itchy, rough or painful areas of skin.

2. What you need to know before you use MACEPATAN FATTY OINTMENT

Do not use MACEPATAN FATTY OINTMENT:

- if you are hypersensitive (allergic) to methylprednisolone aceponate or any of the other ingredients of MACEPATAN FATTY OINTMENT (listed in section 6),
- on skin areas that are affected by tuberculosis or syphilis infection,
- on skin areas that are red or inflamed after being given a vaccine,
- if you have a viral infection (e.g. chickenpox, herpes simplex, vaccinia or shingles),
- if you are pregnant (see section Pregnancy, breastfeeding and fertility),
- in children under the age of 4 months.

MACEPATAN FATTY OINTMENT should not be applied to your face if you have:

- rosacea, a skin condition that causes redness or small, red, pus-filled bumps,
- skin ulcers, presenting as sores on the skin,
- atrophic skin diseases, presenting thinning of skin,
- acne vulgaris, a condition causing papules, pustules, nodules, or cysts on the skin,
- perioral dermatitis, a skin condition causing swelling or rashes around the mouth.

Warnings and precautions

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Take special care with MACEPATAN FATTY OINTMENT:

- Long term treatment with MACEPATAN FATTY OINTMENT should be avoided as this may cause thinning of the skin, loss of elasticity, stretch marks (striae), small dilated blood vessels near the surface of the skin, 'spider veins' (telangiectasia) and bruising of the skin (ecchymoses). More likely to occur when used on the face or when a dressing is used over it. Use MACEPATAN FATTY OINTMENT for the shortest possible time, especially in children.
 - Acne eruptions can occur while on treatment with MACEPATAN FATTY OINTMENT.
 - Thinning of the skin can occur, this is known as atrophy, treatment should be stopped and you will need to discuss with your doctor.
 - You should not use MACEPATAN FATTY OINTMENT under airtight and watertight materials including bandages, poorly breathable dressings, clothing or nappies.
 - If you use a large amount of MACEPATAN FATTY OINTMENT, or if it is applied to wide areas of the body, or if dressings are used to close off the affected area, the medicine may enter your blood (systemic absorption), and may affect important body processes such as moods, emotion, digestion, energy storage and other processes.
 - These effects are more likely to be severe in children and may affect their growth or increase pressure inside their skull causing vision disturbances and headaches.
- Use as little as possible, especially in children.

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- If your doctor diagnoses that your skin disease is accompanied by bacterial or fungal infections, additional specific therapy is required. Stop MACEPATAN FATTY OINTMENT and talk to your doctor if the infection spreads or gets worse.
- MACEPATAN FATTY OINTMENT should not be applied to the face if you have any lesions or irregularity, unless directed by your doctor.
- You should not get MACEPATAN FATTY OINTMENT into your eyes or mouth, open wounds or on mucosal surfaces (e.g. the anal and genital area).
- Your doctor may regularly monitor your treatment with MACEPATAN FATTY OINTMENT.
- MACEPATAN FATTY OINTMENT may cause pus-filled blisters if it is used to treat psoriasis.
- You should not apply MACEPATAN FATTY OINTMENT into the creases of your skin.
- If you experience blurry vision or other visual disturbances, you should tell your doctor.
- You should not use large doses or extensive applications, for prolonged periods on the skin around the eyes as this can cause glaucoma (increase in pressure in the eye).
- You should not use MACEPATAN FATTY OINTMENT under the nappy area of infants.

Children

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There is no experience with MACEPATAN FATTY OINTMENT in children younger than four months. It should not be applied to infants and young children.

Other medicines and MACEPATAN FATTY OINTMENT

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 MACEPATAN FATTY OINTMENT if you are pregnant.

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.

If you are breastfeeding your baby while using MACEPATAN FATTY OINTMENT avoid treatment over large areas, prolonged use or occlusive dressings. In order to avoid possible ingestion by your baby you should not apply MACEPATAN FATTY OINTMENT to your chest area during breastfeeding.

Driving and using machines

MACEPATAN FATTY OINTMENT may cause blurred vision. You should not drive, use machinery or perform any tasks that require concentration until you are certain that MACEPATAN FATTY OINTMENT does not adversely affect your ability to do so safely (see section 4).

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3. How to use MACEPATAN FATTY OINTMENT

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

Always use MACEPATAN FATTY OINTMENT exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For external use only (outside the body).

MACEPATAN FATTY OINTMENT is applied thinly once per day to the diseased areas of skin.

In general, you should not use MACEPATAN FATTY OINTMENT for longer than 12 weeks in adults and 4 weeks in children.

Your doctor will tell you how long your treatment with MACEPATAN FATTY OINTMENT will last. Do not stop treatment early. If you have the impression that the effect of MACEPATAN FATTY OINTMENT is too strong or too weak, tell your doctor or pharmacist.

If you take more MACEPATAN FATTY OINTMENT than you should

In the event of overdosage (from prolonged use or accidentally swallowing MACEPATAN FATTY OINTMENT), consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use MACEPATAN FATTY OINTMENT

If you have missed an application of MACEPATAN FATTY OINTMENT, apply the missed application as soon as you remember. Do not apply a double amount of MACEPATAN

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FATTY OINTMENT. However, if it is nearly time for the next application, skip the missed application. If you have forgotten to apply several applications, contact your doctor without delay.

If you stop using MACEPATAN FATTY OINTMENT

Long term continuous or inappropriate use of MACEPATAN FATTY OINTMENT can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). Symptoms may include intense redness, stinging and burning that can spread beyond the initial treatment area. If this occurs a few days or weeks after stopping treatment with MACEPATAN FATTY OINTMENT, then contact your doctor immediately.

4. Possible side effects

MACEPATAN FATTY OINTMENT can have side effects.

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

If any of the following happens, stop using MACEPATAN FATTY OINTMENT 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.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Hair follicle inflammation (folliculitis),
- burning sensation or itch (pruritus) at the site of application.

Less frequent side effects:

- Increased pressure around the brain (benign intracranial hypertension),
- thinning of the skin, loss of elasticity of the skin, small dilated blood vessels that can occur near the surface of the skin or 'spider veins' (telangiectasia),
- small bruises caused by blood leaking from broken blood vessels into the tissues of the skin or mucous membranes (ecchymoses),
- breaks in the skin similar to a cut (skin fissures),
- reddening, dryness, blisters, irritation, rash, papules at the application site.

Side effects with an unknown frequency:

- Blurred vision,
- a disorder that occurs when the adrenal glands don't make enough of certain hormones (adrenal suppression),
- growth retardation in children,

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- Cushing syndrome, when the body has too much of the hormone cortisol for a long time,
- increased hair growth (hypertrichosis), skin inflammation in the area of the upper lip and chin (perioral dermatitis),
- acne (pimples).
- 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.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of MACEPATAN FATTY OINTMENT.

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5. How to store MACEPATAN FATTY OINTMENT

Store all medicines out of reach of children.

Store at or below 25 °C.

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).

Keep in the original container until required for use.

Keep the tube container well closed.

6. Contents of the pack and other information

What MACEPATAN FATTY OINTMENT contains

The active substance in each 1 g of MACEPATAN FATTY OINTMENT is 1 mg methylprednisolone aceponate.

The other ingredients are hydrogenated castor oil, liquid paraffin, microcrystalline wax, white soft paraffin.

What MACEPATAN FATTY OINTMENT looks like and contents of the pack

MACEPATAN FATTY OINTMENT is a white to yellowish translucent ointment.

20 g or 50 g is packed in a closed end nozzle lacquered aluminium tube with white polypropylene cap with piercing tip, contained in an outer carton.

Not all packs or pack sizes may be marketed.



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Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

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Hotline: 0800 122 912

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Registration number

59/13.4.1/0670

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