

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

MACEPATAN CREAM 1 mg/g

Methylprednisolone aceponate

Benzyl alcohol 1 % *m/m*

Cetostearyl alcohol 60 mg/g

Butyl hydroxy toluene 0,050 mg/g

Read all of this leaflet carefully before you start using MACEPATAN 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.
- MACEPATAN 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 MACEPATAN CREAM is and what it is used for
2. What you need to know before you use MACEPATAN CREAM
3. How to use MACEPATAN CREAM
4. Possible side effects
5. How to store MACEPATAN CREAM
6. Contents of the pack and other information

1. What MACEPATAN CREAM is and what it is used for

MACEPATAN CREAM belongs to a group of medicines called corticosteroids and is used for the treatment of certain skin conditions that cause pain or swelling (inflammatory skin conditions).

MACEPATAN CREAM is used to treat a variety of eczemas, which are skin conditions that cause dry, sensitive, swollen (inflamed), itchy, rough or painful areas of skin.

2. What you need to know before you use MACEPATAN CREAM

Do not use MACEPATAN CREAM

- if you are hypersensitive (allergic) to methylprednisolone aceponate or any of the other ingredients of MACEPATAN CREAM (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 CREAM 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

Take special care with MACEPATAN CREAM:

- Long term treatment with MACEPATAN CREAM should be avoided as this may cause thinning of the skin, loss of elasticity of the skin, stretch marks (striae), small dilated blood vessels that can occur near the surface of the skin or 'spider veins' (telangiectasia) or bruising of the skin (ecchymoses). Use MACEPATAN CREAM for the shortest possible time, especially in children.
- Acne eruptions can occur while on treatment with MACEPATAN CREAM.
- 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 CREAM under airtight and watertight materials including bandages, poorly breathable dressings, clothing or nappies.
- If you use a large amount of MACEPATAN CREAM, 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. Use as little as possible, especially in children.

- If your doctor diagnoses that your skin disease is accompanied by bacterial or fungal infections, additional specific therapy is required. Stop MACEPATAN CREAM and talk to your doctor if the infection spreads or gets worse.
- MACEPATAN CREAM should not be applied to the face if you have any lesions or irregularity, unless directed by your doctor.
- You should not get MACEPATAN CREAM 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 CREAM.

- MACEPATAN CREAM may cause pus-filled blisters if it is used to treat psoriasis.
- You should not apply MACEPATAN CREAM 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 CREAM under the nappy area of infants.

Children

There is no experience with MACEPATAN CREAM in children younger than four months. Ideally it should not be applied to infants and young children.

Other medicines and MACEPATAN 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 MACEPATAN CREAM 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 CREAM avoid treatment over large areas, prolonged use or occlusive dressings. In order to avoid possible ingestion by

your baby you should not apply MACEPATAN CREAM to your chest area during breastfeeding.

Driving and using machines

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

MACEPATAN CREAM contains

Benzyl alcohol and cetostearyl alcohol which may cause local skin reactions and irritations (e.g. contact dermatitis) MACEPATAN CREAM also contains butyl hydroxy toluene which may cause irritation to the eyes and mucous membranes in addition to local skin reactions.

3. How to use MACEPATAN CREAM

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

Always use MACEPATAN CREAM 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 CREAM is applied thinly once per day to the diseased areas of skin.

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

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

If you take more MACEPATAN CREAM than you should

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

If you forget to use MACEPATAN CREAM

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

Long term continuous or inappropriate use of MACEPATAN CREAM 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.

4. Possible side effects

MACEPATAN CREAM can have side effects.

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

If any of the following happens, stop using MACEPATAN 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 MACEPATAN CREAM. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Burning sensation or itch at the site of application.

Less frequent side effects:

- 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), bruising of the skin (ecchymosis), bacterial skin infections (impetigo), greasy skin,
- reddening, dryness, blisters, irritation, rash, papules at the application site (erythema),
- accumulation of fluid causing swelling (peripheral oedema).
- large, painful ulcers on the skin (pyoderma),
- breaks in the skin similar to a cut (skin fissures),
- acne (pimples).

Side effects with an unknown frequency:

- Hair follicle inflammation (folliculitis), increased hair growth (hypertrichosis), skin inflammation in the area of the upper lip and chin (perioral dermatitis),
- blurred vision,
- 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: <https://www.sahpra.org.za/Publications/Index/8>

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 CREAM.

5. How to store MACEPATAN CREAM

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).

6. Contents of the pack and other information

What MACEPATAN CREAM contains

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

The other ingredients are benzyl alcohol, butyl hydroxy toluene, cetostearyl alcohol, decyl oleate, disodium edetate, glycerol, glycerol monostearate, hard fat, macrogol stearate, purified water, Softisan.

Preservative: Benzyl alcohol 1 % *m/m*

Cetostearyl alcohol 60 mg/g

Butyl hydroxy toluene 0,050 mg/g

What MACEPATAN CREAM looks like and contents of the pack

MACEPATAN CREAM is a white to yellowish opaque cream.

15 g, 20 g or 50 g packed in lami collapsible tube with polypropylene cap.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191



Hotline: 0800 122 912

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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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