

1.3.2.1 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

METIDERM CREAM, 1 mg/g (0,1 % *m/m*) cream

Methylprednisolone aceponate

Read all of this leaflet carefully before you start using METIDERM CREAM

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other healthcare provider.
- METIDERM CREAM has been prescribed for you personally and 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 METIDERM CREAM is and what it is used for
2. What you need to know before you use METIDERM CREAM
3. How to use METIDERM CREAM
4. Possible side effects
5. How to store METIDERM CREAM
6. Contents of the pack and other information

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

The active ingredient in METIDERM CREAM belongs to the group of medicines called corticosteroids. The corticosteroid in METIDERM CREAM is suitable to put on the skin. It

is therefore called a topical corticosteroid, which is sometimes shortened to topical steroid.

METIDERM CREAM relieves inflammation, redness, swelling, itching and irritation of the skin in various types of eczema (skin disorders that are non-contagious and inflammatory).

When METIDERM CREAM is used correctly, it is a safe and effective treatment for skin disorders.

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

Do not use METIDERM CREAM:

- if you are hypersensitive (allergic) to methylprednisolone aceponate (MPA) or to any of the other ingredients of METIDERM CREAM (listed in section 6);
- on tuberculous (TB) or syphilis lesions, viral infections (cold sores, chickenpox, smallpox, shingles);
- on skin areas affected by a skin inflammation that is red/rosy in colour (rosacea), ulcers, inflamed diseases of the sebaceous glands (acne vulgaris) or skin diseases accompanied by a thinning of the skin (atrophic skin diseases);
- on specific skin inflammation in the area of the upper lip and chin (perioral dermatitis);
- if you are pregnant (see “Pregnancy and breastfeeding”);
- in children under four months due to lack of experience.

Warnings and precautions

- **Do not apply METIDERM CREAM to any skin crease areas.**

- Make sure that you see your doctor on the follow-up dates scheduled for you. Your doctor will tell you if you may continue the treatment.
- Side effects can develop if METIDERM CREAM is used for too long, is too potent, is applied too frequently or if too much of the cream is applied to the affected area. At the same time, underuse can prolong treatment duration or increase certain side effects. Talk to your doctor if you are not sure how to proceed with your treatment.

Tell your doctor before using/during treatment with METIDERM CREAM:

- if you develop signs of an allergic reaction (see “Possible side effects” for more information);
- if you breastfeed your baby. See “Pregnancy and breastfeeding”;
- if you think your skin is also infected, ask your doctor to look at it. Should you have a concomitant bacterial or fungal infection, additional specific therapy is required. Tell your doctor if the infection spreads or gets worse during treatment;
- if you have psoriasis, as treatment with METIDERM CREAM may cause the disease to worsen to the pustular form (eruption of pimples).

To reduce the risk of side effects:

- you should not get METIDERM CREAM into your eyes, an open wound or mucosal surfaces;
- Avoid prolonged use of METIDERM CREAM on sensitive areas such as the face and genitals.
- Except if advised otherwise by your doctor, you should avoid using METIDERM CREAM on large areas of the body or for prolonged periods of time, as this will significantly increase the risk of side effects. Long-term treatment may cause skin thinning, loss of

elasticity, dilation of small blood vessels and blemishes, particularly if the application area is covered with a dressing.

- you should not use METIDERM CREAM on damaged skin;
- seek medical advice before using METIDERM CREAM on a new body area, as some areas of the body are more prone to side effects;
- use as little as possible, especially in children;
- you should not use METIDERM CREAM under air- and watertight materials including bandages, poorly breathable dressings, clothing or nappies.

Vision disturbances

If you use METIDERM CREAM on extensive areas for long periods of time or if you apply it around or near the eyes, you may develop glaucoma. Contact your doctor if you experience blurred vision or other visual disturbances.

Barrier methods of contraception

If METIDERM CREAM is applied to the anal or genital areas, some of its ingredients may cause damage to latex products such as condoms or diaphragms. Therefore, these products may no longer be effective as contraception or as protection against sexually transmitted diseases such as HIV infection. Talk to your doctor or pharmacist, if you require more information.

Rebound flares after discontinuation of treatment

Very infrequent cases of severe skin reactions have been reported in long-term users of topical corticosteroids after they stop using them. If your skin worsens shortly after stopping a topical corticosteroid, do not start treatment again without consulting your doctor, unless they have previously advised you should do so (see "Possible side effects" for more information).

Children

Long-term use of METIDERM CREAM may interfere with growth and development in children and cause a Cushingoid state. Cushing syndrome can result in exaggerated facial roundness, weight gain around the midsection and upper back, thinning of your arms and legs, easy bruising and stretch marks. You should not use METIDERM CREAM under nappies as this enhances absorption.

Other medicines and METIDERM CREAM

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

Interactions of METIDERM CREAM with other medicines are not known so far. However, tell your doctor if you are using, have recently used or might use any other medicines.

Pregnancy and breastfeeding

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 METIDERM CREAM.

Pregnancy

There is not adequate information available on the use of METIDERM CREAM in pregnant women; METIDERM CREAM should therefore not be used during pregnancy (see “Do not use METIDERM CREAM”).

Breastfeeding

It is not known how much METIDERM CREAM is absorbed in breast milk. Your doctor will decide if you should use METIDERM CREAM while breastfeeding. Do not apply

METIDERM CREAM on the breasts. Do not treat large areas, do not use dressings to cover the area and avoid long-term use. Do not bring your baby into contact with the treated areas to avoid possible ingestion by the baby.

Driving and using machines

The application of METIDERM CREAM does not affect the ability to drive or use machines.

METIDERM CREAM contains butylhydroxytoluene (E321), cetostearyl alcohol and benzyl alcohol

METIDERM CREAM contains butylhydroxytoluene 0,006 % *m/m*, which may cause local skin reactions (e.g., contact dermatitis) or irritation to the eyes and mucous membranes, and cetostearyl alcohol 3 % *m/m*, which may cause local skin reactions (e.g. contact dermatitis).

METIDERM CREAM also contains benzyl alcohol 1 % *m/m*. Benzyl alcohol may cause allergic reactions.

3. How to use METIDERM CREAM

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

Always use METIDERM CREAM exactly as your doctor has told you. Check with your doctor if you are not sure.

The usual dose is:

- apply METIDERM CREAM thinly once per day to the affected areas of skin;
- always keep the treatment period as short as possible. The duration of use should not exceed 12 weeks in adults and 4 weeks in children.

If your skin dries out excessively using METIDERM CREAM, ask your doctor about switching to one of the formulations with a higher fat content.

If you have an impression that the effect of METIDERM CREAM is too strong or too weak, talk to your doctor or pharmacist.

If you use more METIDERM CREAM than you should

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

No information is available on a one-time overdose (too large amount or too large skin area). Excessive applications over a long time may intensify the side effects (see “Possible side effects”).

If you forget to use METIDERM CREAM

Do not use twice as much to make up for forgotten individual doses.

Continue using it as prescribed by your doctor.

If you stop using METIDERM CREAM

Please contact your doctor or pharmacist for more information on the duration and discontinuation of treatment with METIDERM CREAM.

4. Possible side effects

METIDERM CREAM can have side effects.

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

If any of the following happens, stop using METIDERM 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.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- a burning sensation and itching at the site of application

Less frequent side effects:

- allergic skin reaction (contact dermatitis)
- application site skin dryness, application site erythema (red skin), application site blisters, application site hair follicle inflammation (folliculitis), application site rash, application site tingling or prickling sensation
- application site cellulitis (skin infection), application site swelling, application site irritation
- pyoderma (skin infection producing pus), skin cracks, telangiectasia (swelling of the small blood vessels in the skin),
- skin atrophy (thinning of the skin), acne
- fungal skin infection

Side effects with unknown frequency:

- blurred vision
- stretch marks
- increased hair growth
- specific skin inflammation in the area of the upper lip and chin (perioral dermatitis)
- skin discolouration
- rebound flares after long-term treatment is discontinued, i.e., dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area.

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 (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of METIDERM CREAM.

5. How to store METIDERM CREAM

Store all medicines out of reach of children.

Store at or below 25 °C. Keep the tube tightly closed. After first opening of the tube, the in-use stability is 6 months.

Do not refrigerate or freeze.

Do not use after the expiry date stated on the tube and carton.

Return all unused medicine to your pharmacist.

Do not throw away any medicines in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What METIDERM CREAM contains

- The active substance is: methylprednisolone aceponate (MPA).

Each 1 g cream contains methylprednisolone aceponate 1 mg (0,1 % *m/m*). (This corresponds to 0,792 mg methylprednisolone base per 1 g cream.)

- The other ingredients are:

Glycerol 85 %, disodium edetate, purified water, benzyl alcohol 1 % *m/m* (preservative), hard fat (such as Softisan 378), cetostearyl alcohol 3 % *m/m* (antioxidant and preservative), glycerol monostearate 40-55 %, hard fat (such as Witepsol 35 II), macrogol stearate 40, butylhydroxytoluene 0,006 % *m/m* (preservative), decyl oleate.

What METIDERM CREAM looks like and contents of the pack

A homogenous white to off-white spreadable cream for topical application.

METIDERM CREAM is available in tubes of 15, 20, 25, 30, 50, 60, or 100 g of cream. Tubes are made of pure aluminium; with interior wall coated with epoxy resin, and with an epoxy based external coating, fold seal ring is made of polyamide-based heat sealable material. The screw cap is made of high-density polyethylene (HDPE).

Not all pack sizes may be marketed.

Holder of the Certificate of Registration

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Access to the corresponding Professional Information

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