PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

ADVANTAN® MILK, 1 mg / g, Emulsion
Methylprednisolone aceponate

Read all of this leaflet carefully before you start using ADVANTAN® MILK

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ADVANTAN® MILK 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 ADVANTAN® MILK is and what it is used for
2. What you need to know before you use ADVANTAN® MILK
3. How to use ADVANTAN® MILK
4. Possible side effects
5. How to store ADVANTAN® MILK
6. Contents of the pack and other information

1. What ADVANTAN® MILK is and what it is used for

ADVANTAN® MILK contains methylprednisolone aceponate which is an anti-inflammatory medicine (a corticosteroid) that is intended to be used on the skin. It reduces the inflammation and allergic reaction of the skin. Therefore, it lessens redness(erythema), fluid build-up (oedema) and fluid oozing from the inflamed skin. It also relieves the itchiness, burning sensation or pain you may feel. ADVANTAN® MILK is used for treatment of different types of eczema (acute exogenous and endogenous eczema). Eczema is a skin condition that makes your skin red and itchy.

2. What you need to know before you use ADVANTAN® MILK

Do not use ADVANTAN® MILK

- if you are allergic (hypersensitive) to methylprednisolone aceponate (MPA) or any of the other ingredients listed in section 6.

- if you are pregnant.
- if you have a tuberculosis (TB) or syphilis related skin conditions.
- if you have a viral infection affecting the skin, such as herpes or varicella that causes painful sores (ulcers) on the skin.
- if you have a bacterial or fungal skin infection/disease.
- if you have skin ulcers in the area to be treated.
- if you have skin affected by rosacea (rosy/red coloured skin in the face, often accompanied by small, red, pus-filled bumps).
- if you have skin affected by acne vulgaris (when hair follicles plug with oil and dead skin cells causes acne/pimples).
- if you have an inflammatory rash involving the skin around the mouth (perioral dermatitis).
- if you have a skin disease accompanied by a thinning of the skin (atrophic skin diseases).
- if you have a skin reaction following vaccination in the area to be treated.

Warnings and precautions

Take special care with ADVANTAN® MILK:

- Long-term treatment should be avoided as this may cause changes in the skin that will lead to thinning and loss of elasticity.
- Long-term use may also cause spider veins (telangiectasia), discolouration of the skin resulting from bleeding underneath (bruising/ ecchymoses) and dilated blood vessels on the surface of the skin.
- Corticosteroids like ADVANTAN® MILK shows strong effects on the body. It is not recommended to use ADVANTAN® MILK on large areas of the body, on damaged skin, or for prolonged periods of time as this will significantly increase the risk of side effects. These effects are most likely to be worse in children.
- If your skin disease is accompanied by bacterial or fungal infections, additional specific medication will be prescribed by your doctor. Notify your doctor if the infection spreads or gets worse.
- Avoid contact with the eyes, deep open wounds and mucus membranes such as the lining of the mouth, nose, eyelids, and parts of the male and female genitals.
- Breastfeeding mothers must not apply ADVANTAN® MILK on the breasts and on not more than 40 % of the body surface.
- Use with care when applied to areas of the face and only use ADVANTAN® MILK for short periods as it may cause rosacea-like conditions (rosy/red coloured skin in the face, often accompanied by small, red, pus-filled bumps).
- Application of ADVANTAN® MILK under air- and water-tight dressing increases the risk of side effects. Treatment under these conditions should be avoided unless indicated by your doctor.

- Diapers as well as areas where two skin areas touch or rub together (such as skin folds/creases) might represent occlusive conditions.
- Glaucoma (increase of pressure in the eye) may develop when ADVANTAN® MILK is used on large areas, or extensive applications over a prolonged period, with air- and water-tight dressings or when applied to the skin around the eyes.
- Your vision may be affected by the use of ADVANTAN® MILK as blurred vision has been reported with the use of corticosteroids such as in ADVANTAN® MILK.
- The excipient (caprylic-capric-myristic-stearic triglyceride) in ADVANTAN® MILK may cause problems with latex products such as condoms and diaphragms.
- ADVANTAN® MILK contains benzyl alcohol which may cause allergic reactions or mild skin irritation.
- If there is a worsening of your condition during use consult your prescriber – 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 prescriber unless your prescriber 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.

Children

ADVANTAN® MILK should not be used in the nappy areas in infants and ideally not be used in infants and young children.

Other medicines and ADVANTAN® MILK

No information is available.

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 health care provider for advice before taking this medicine.

Pregnancy

The safety of this medicines in pregnancy has not been established.

As a general rule, topical preparations containing corticosteroids should not be applied during the first three months of pregnancy. Large-area, prolonged use or use of air- and water-tight dressings should be avoided in pregnancy.

Do not use ADVANTAN® MILK if you are pregnant.

Breastfeeding

The safety of this medicines in breastfeeding has not been established.

Do not use ADVANTAN® MILK if you are breastfeeding unless your doctor considers it necessary.

If your doctor recommends the use of ADVANTAN® MILK while breast-feeding, do not apply the medicine on the breasts. Do not bring your baby into contact with the treated areas. Large area, prolonged use or use of air- and water-tight dressings should be avoided while breastfeeding.

Driving and using machines

ADVANTAN® MILK has no influence on the ability to drive and use machines.

3. How to use ADVANTAN® MILK

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

Always use ADVANTAN® MILK exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

ADVANTAN® MILK is to be used only as necessary and applied thinly once per day to the affected areas of the skin and rubbed in lightly.

In general, the duration of use should not exceed two weeks. Your doctor will tell you how long your treatment with ADVANTAN® MILK will last.

If your skin dries out excessively with ADVANTAN® MILK ask your doctor about switching to one of the formulations with a higher fat content (ADVANTAN® Ointment or ADVANTAN® Fatty Ointment).

If you have the impression that the effect of ADVANTAN® MILK is too strong or too weak, tell your doctor or pharmacist.

If you use more ADVANTAN® MILK than you should

No risk is to be expected from a one-time overdose (too large amount or too large skin area) or accidental oral ingestion (when swallowed).

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

If you forget to use ADVANTAN® MILK

Do not use the double amount the next time, but continue the use as prescribed by your doctor.

If you stop using ADVANTAN® MILK

Don’t stop using ADVANTAN® MILK without talking to your doctor first.

4. Possible side effects

ADVANTAN® MILK can have side effects.

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

ADVANTAN® MILK, may occasionally, lead to local skin irritations such as a mild burning sensation. Less frequently, itching, redness of the skin, dry skin, scaling, inflammation and infection of hair follicles may arise.

Allergic reactions to the components of ADVANTAN® MILK may occur.

The following side effects have been reported:

Frequent:

- Burning sensation at the site of application.

Less frequent:

- Eczema.
- Skin exfoliation.
- Skin tears/cracks (fissures).
- Pain at the site of application
- Small fluid filled sacks/blisters (vesicles) at the site of application
- Itching (pruritus) at the site of application
- Small bumps containing fluid or pus (pustules) at the site of application
- Application site erosion (sores).

Frequency unknown:

- 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.

As with other topical corticosteroids (as in ADVANTAN® MILK) the following local side effects may occur:

- Thinning of the skin (atrophy)
- Site dryness
- Redness of the skin
- Stretch marks (striae)

- Hair follicle inflammation (folliculitis)
- Swelling of the small blood vessels in the skin
- Increased body hair growth (hypertrichosis)
- Specific skin inflammation in the area of the upper lip and chin (perioral dermatitis)
- Changes in skin colour
- Allergic skin reaction (contact dermatitis).
- Acne (pimples)

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 more information on the safety of ADVANTAN® MILK.

5. How to store ADVANTAN® MILK

Store all medicines out of reach of children.

Store at or below 30 °C.

Do not use after the expiry date.

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 ADVANTAN® MILK contains

The active substance is methylprednisolone aceponate.

Each 1 g ADVANTAN® MILK contains 1 mg methylprednisolone aceponate.

The other ingredients are: Triglycerides (medium-chain), caprylic-capric-myristic-stearic triglyceride, macrogol-2-stearylether, macrogol-21-stearylether, benzyl alcohol, disodium edetate, glycerol (85%), water (purified).

What ADVANTAN® MILK looks like and contents of the pack

ADVANTAN® MILK is a white, opaque emulsion.

ADVANTAN® MILK is packed in tubes of 20 g or 50 g made of polyethylene laminated aluminium tube with a high-density polyethylene white shoulder and a white polypropylene screw cap.

Not all pack sizes may be marketed

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