1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

MYLOCORT CREAM 1,0 g/100 g

Hydrocortisone acetate

MYLOCORT OINTMENT 1,0 g/100 g

Hydrocortisone acetate

Read all of this leaflet carefully before you start using MYLOCORT

MYLOCORT is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use MYLOCORT carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share MYLOCORT with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet

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

1. What MYLOCORT is and what it is used for

MYLOCORT contains a medicine called hydrocortisone.

Hydrocortisone has topical anti-inflammatory, anti-pruritic (anti-itchiness), anti-allergic and vasoconstrictive (constriction of the blood vessels) activities and is used in the treatment of various skin conditions.

MYLOCORT is used for the temporary relief of itching caused by minor skin irritations due to:

- Eczema.
- Insect Bites.
- Poisonous plants.
- Soaps.
- Detergents.
- Cosmetics.
- Jewellery.
- Skin condition caused by increased secretion of the sebaceous (oil forming) glands (seborrheic dermatitis).
- The relief of external genital and anal itching in patients older than 12 years of age (see section 2 ‘Do not use MYLOCORT’).

2. What you need to know before you use MYLOCORT

Do not use MYLOCORT:

- If you are hypersensitive (allergic) to hydrocortisone or any other ingredients of MYLOCORT (see section 6).
- In the presence of vaginal discharge.
- For cosmetic purposes.
- For anal itching accompanied by bleeding.
- For nappy rash.

- For children under the age of 12 years for indications pertaining to genital and anal use.
- For children under the age of 2 years.
- For untreated bacterial, viral or fungal infections.
- For tuberculosis (an infectious disease caused by bacteria) of the skin and varicose ulcers (a wound on the leg or ankle caused by abnormal or damaged veins).
- For scabetic infections caused by the scabies mite.
- For rosacea (flushing of the skin on the face).
- For perioral dermatitis (rash affecting skin around the mouth).
- If you are pregnant or breastfeeding your baby (See section 'Pregnancy and breastfeeding' below).
- For use around/on the eyes or on broken skin.
- For acne.

Warnings and precautions

Take special care with MYLOCORT:

- MYLOCORT is intended for external use only.
- MYLOCORT should be kept away from the eyes.
- MYLOCORT should be used cautiously in facial diseases of the skin and only for short periods of time (not longer than 7 days).
- Long term use of MYLOCORT can cause thinning of the skin which can cause loss of elasticity, widening of small skin blood vessels, bruising or bleeding into the skin and reduced pigmentation.
- Absorption throughout the body may occur when:
  - large quantities are used.
  - applied to wide areas of the body.
  - applied to damaged skin.

- a dressing completely covering the wounds is applied.
- applied to skin folds and moist areas.
- applied to the nappy areas in young children.

- Absorption throughout the body can cause failure of a part of the adrenal gland to produce adequate steroid hormones; these effects are more likely to be severe in children.
- As a result growth retardation may occur, a Cushingoid state may be produced (having the constellation of signs and symptoms caused by an excess of cortisol hormone, typical features are facial puffiness, weight gain, thinning of the skin, weakness, bruising, hypertension, diabetes, thin weak bones) or moderately raised pressure inside the skull has been rarely reported.
- If treatment continues longer than two weeks, the risk of side effects throughout the body will increase especially in children.
- MYLOCORT must not be used for diseases of the skin in younger children including nappy rash. The nappy can act as a dressing completely covering the wound as increased absorption can occur (see section 2).
- If a bacterial/germ infection is present, then a suitable antimicrobial should be used with MYLOCORT.
- MYLOCORT CREAM contains chlorocresol amongst the excipients which may cause allergic reactions, discontinue treatment if this occurs.
- MYLOCORT should be used with caution in psoriasis (skin disease with raised rough scaly areas).
- Do not put MYLOCORT into the rectum by using fingers or any mechanical device or applicator.
- Do not use MYLOCORT for longer than 7 days.
- Rebound flares (topical steroid withdrawal syndrome) may occur when stopping treatment with MYLOCORT, if used incorrectly (see ‘If you stop using MYLOCORT’).

Children and adolescents

Do not use in children under the age of two.

Do not use in children under the age of 12 years for indications pertaining to genital and anal use.

Other medicines and MYLOCORT

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

No interactions have been reported with the use of MYLOCORT.

Pregnancy and breastfeeding

The safety of MYLOCORT during pregnancy and whilst breastfeeding has not been established.

You should not use MYLOCORT if you are pregnant or breastfeeding your baby (see section 'Do not use MYLOCORT'). 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 MYLOCORT.

Driving and using machines

MYLOCORT may cause visual impairment and could affect your ability to drive or use machinery. You should not drive, use machinery or perform any tasks that require concentration until you are certain that MYLOCORT does not adversely affect your ability to do so safely.

It is not always possible to predict to what extent MYLOCORT 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 MYLOCORT affects you (see section 4).

MYLOCORT CREAM contains chlorocresol

Chlorocresol in MYLOCORT CREAM may cause local skin reactions.

3. How to use MYLOCORT

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

Always apply MYLOCORT exactly as described in this leaflet or as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are not sure.

After thorough cleaning of the affected skin, a thin layer of MYLOCORT is applied by smoothing gently into the affected area/s. No additional benefit is gained by vigorous rubbing.

MYLOCORT is usually applied four times a day until improvement occurs, when the frequency of application may be reduced.

MYLOCORT CREAM is usually suitable for moist or fluid-filled blisters on the skin (weeping surfaces), whereas MYLOCORT OINTMENT should be considered for dry, scaly or lichenified (skin that has become thickened and leathery) conditions.

Your doctor will tell you how long your treatment with MYLOCORT will last. If you have the impression that the effect of MYLOCORT is too strong or too weak, tell your doctor or pharmacist.

Do not use this product for longer than 7 days.

Do not put this product into the rectum by using fingers or any mechanical device or applicator (see section 2).

If you use more MYLOCORT than you should

If you accidently swallow MYLOCORT, contact your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use MYLOCORT

If you forget to apply MYLOCORT at the correct time, do so as soon as you remember. Do not apply a double dose to make up for forgotten individual doses.

If you stop using MYLOCORT

Long term continuous or inappropriate use of MYLOCORT 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

MYLOCORT can have side effects.

Not all side effects reported for MYLOCORT are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using MYLOCORT, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop using MYLOCORT 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 MYLOCORT. 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:

- A build-up of pressure around the brain (benign intracranial hypertension) that can present with symptoms such as headache behind the eyes, shoulder and neck pain and ringing in the ears,

- a decrease in the level of the hormone cortisol in your blood (suppression of the hypothalamic pituitary adrenal axis) that can present with symptoms such as depression, weakness, fatigue, and weight loss.

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:

- Loss of skin collagen,
- thinning of the skin,
- loss of elasticity of the skin,
- widening of the small blood vessels,
- bruising or bleeding into the skin,
- skin is lighter than usual in deeply pigmented skin.

Side effects with an unknown frequency:

- 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:** 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 MYLOCORT.

5. How to store MYLOCORT

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Keep in original packaging until required for use.

Do not use after the expiry date printed on the tube or carton.

Return all unused medicine to your pharmacist.

Do not store in a bathroom.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MYLOCORT contains

MYLOCORT CREAM: Each 100 g of cream contains 1,0 g hydrocortisone acetate.

The other ingredients are chlorocresol, emulsifying wax, purified wax and yellow soft paraffin.

Preservative: Chlorocresol 0,1 % *m/m*

MYLOCORT OINTMENT: Each 100 g of ointment contains 1,0 g hydrocortisone acetate.

The other ingredients are liquid paraffin and white soft paraffin.

What MYLOCORT looks like and the contents of the pack

MYLOCORT CREAM is a smooth white to off white cream.

MYLOCORT OINTMENT is a smooth off-white Vaseline-like ointment.

MYLOCORT CREAM: 25 g is filled into an epoxy-lined aluminium sealed tube, sealed with a high-density polyethylene screw-cap and placed in a unit cardboard carton together with a leaflet.

MYLOCORT OINTMENT: 25 g is filled into an epoxy-lined aluminium sealed tube, sealed with a high-density polyethylene screw-cap and placed in a unit cardboard carton together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

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Hotline: 0800 122 912 (South Africa)

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31 December 2023

Registration numbers

MYLOCORT CREAM: P/13.4.1/93

MYLOCORT OINTMENT: P/13.4.1/112

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

Namibia: NS1 MYLOCORT CREAM: 90/13.4.1/001624 MYLOCORT OINTMENT: 90/13.4.1/001625

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