

Package leaflet: Information for the user
Mildison Lipocream® 1% w/w cream
Hydrocortisone

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Mildison Lipocream is and what it is used for

Mildison Lipocream contains the active substance hydrocortisone, which belongs to the group of mildly potent corticosteroids. These medicines are used to reduce symptoms of inflammation such as itching and redness or flakiness of the skin which may occur in certain skin disorders.

Mildison Lipocream is indicated in adults, children and infants. It is used to treat a variety of skin conditions such as eczema and dermatitis (itching) of all types including atopic (childhood) eczema, photodermatitis (a dermatitis caused by exposure to light), otitis externa (inflammation of the ear canal), dermatitis caused by skin irritants and allergies, intertrigo (inflammation of skin folds), prurigo nodularis (a skin change associated with a nervous condition), seborrhoeic dermatitis (eczema of areas of greasy skin) and insect bite reactions. In general, corticosteroids do not remove the cause of the symptoms.

2. What you need to know before you use Mildison Lipocream

Do not use Mildison Lipocream:

- if you are allergic to hydrocortisone or any of the other ingredients of this medicine (listed in section 6)
- if your skin disorder is caused by a bacterial, viral or fungal infection. Mildison Lipocream may worsen or hide these disorders. Your doctor will check these
- if you have wounds or scaly skin

- if you have skin problems due to syphilis (a sexually transmitted disease) or skin lesions associated with tuberculosis appearing as jelly like nodules or ulcerative nodules
- if the skin around your mouth is inflamed. It might be the result of previous treatment with corticosteroids
- if you have (pubertal) spots
- if you have redness of the facial skin.

Warnings and precautions

Talk to your doctor before using Mildison Lipocream if it was prescribed to:

- treat facial or thin skin as these areas are particularly sensitive to corticosteroids. You should not apply to your eyes or your eyelids
- treat your child (see further information below).

During treatment:

Contact your doctor if you experience blurred vision or other visual disturbances.

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, do not restart using the cream/ointment 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.

Mildison Lipocream contains paraffin. Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Children and adolescents

Long term treatment of children should be avoided where possible. Treatment should be limited to seven days if possible. Your doctor will advise on duration of treatment for your child.

Other medicines and Mildison Lipocream

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding

You should not use Mildison Lipocream if you are pregnant or breast-feeding unless clearly necessary.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

It is not likely that Mildison Lipocream affects your ability to drive or use machines.

Mildison Lipocream contains cetostearyl alcohol, propyl parahydroxybenzoate (E216), and benzyl alcohol.

Mildison Lipocream contains cetostearyl alcohol that may cause local skin reactions (e.g. contact dermatitis) and propyl parahydroxybenzoate (E216) that may cause allergic reactions (possibly delayed).

This medicine also contains 7.5 mg of benzyl alcohol in each gram which is equivalent to 0.75% w/w. Benzyl alcohol may cause allergic reactions and mild local irritation.

3. How to use Mildison Lipocream

Always use this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The recommended dose is a little Mildison Lipocream 2 or 3 times daily.

This medicine is for cutaneous use. Apply a thin layer of Mildison Lipocream to the affected skin. Gently massage the cream into the affected area.

If you use more Mildison Lipocream than you should

If you have used too much Mildison Lipocream the side effects as mentioned in section 4 "Possible side effects" can occur. Contact your doctor, pharmacist or nurse immediately.

If you forget to use Mildison Lipocream

Do not use a double dose to make up for a forgotten dose.

If you stop using Mildison Lipocream

You should always consult your doctor, if you think of stopping treatment.

If you have any further questions on the use of this product, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Mildison Lipocream may cause the following side effects:

Not known (frequency cannot be estimated from the available data)

- Redness of the skin, rash/inflammation, bruising, stretch marks and skin thinning
- Facial spots, redness of the skin around the mouth
- Discolouration of skin
- Skin irritation
- Blurred vision
- Worsening of the skin condition after treatment has stopped (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 the cream is used for a long time it may affect the working of your adrenal glands, symptoms of which may include an increase in weight, puffiness around the face, muscle weakness, dizziness (particularly on standing), excessive hair growth or hair loss. Your doctor should monitor you for any signs or symptoms.

As with other creams of this kind, this is more likely in infants and children or if the skin is covered by bandages or nappies.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Mildison Lipocream

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the tube after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original packaging.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Mildison Lipocream contains

- The active substance is hydrocortisone
- The other ingredients are cetostearyl alcohol, macrogol 25 cetostearylether, liquid paraffin, white soft paraffin, benzyl alcohol, propyl parahydroxybenzoate (E216), anhydrous citric acid, anhydrous sodium citrate and purified water.

What Mildison Lipocream looks like and contents of the pack

Mildison Lipocream is a white cream and is available in 10 g, 15 g, 30 g or 100 g aluminium tubes with plastic screw caps. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder

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