

Package leaflet: Information for the user

Locoid® Ointment

Hydrocortisone butyrate 0.1% w/w

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

1. What Locoid® Ointment is and what it is used for

Locoid Ointment contains the active substance hydrocortisone butyrate. This is a corticosteroid which when made up as an ointment is for use on the skin. This is known as topical application. Topical corticosteroids are ranked as mildly potent, moderately potent, potent and very potent; Locoid Ointment is classed as potent. Topical corticosteroids are able to reduce the inflammation caused by a variety of skin conditions, and so allow it to get better. They can also affect the cause of the condition, which can lead to its healing.

Locoid Ointment is indicated in adults, children and infants over 3 months of age. It is used to treat a variety of skin conditions not caused by micro-organisms. Among these are eczema and dermatitis (itching) of all types including atopic (childhood) eczema, photodermatitis (itching caused by exposure to light) and dermatitis caused by skin irritants and allergies.

It can also be used in the treatment of psoriasis, a condition resulting in thickening of areas of the skin. It is important that you follow your doctor's instructions particularly in psoriasis, and use it only on small areas on the scalp, hands or feet. The original symptoms may return if you stop using Locoid Ointment prematurely.

2. What you need to know before you use Locoid® Ointment

Do not use Locoid Ointment:

- if you are **allergic** to hydrocortisone butyrate or any of the other ingredients of this medicine (listed in section 6).

- if your skin disorder is caused by an untreated **bacterial, viral (e.g. cold sores, herpes, chicken pox), fungal (e.g. athlete's foot), yeast or parasitic (e.g. ringworm) infection**. Locoid Ointment may worsen or hide these disorders. Your doctor will check these.
- if you have skin problems associated with **syphilis (a sexually transmitted disease) or tuberculosis**.
- **if the skin around your mouth is inflamed (perioral dermatitis)**. It might be the result of previous treatment with corticosteroids.
- if you have **pimples or spots (acne)**.
- if you have **redness of the facial skin**.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Locoid Ointment. This is especially important if you intend to:

- treat facial skin, thin skin (e.g. skin of your genitals). These areas of your skin are particularly sensitive to corticosteroids. You should not apply to your eyes or your eyelids.
- use Locoid Ointment at skin folds, under an airtight dressing or on large areas of your skin. If you are using Locoid Ointment under bandages, it should only be on small areas for a short time, and only on the advice of your doctor. Bandages and dressings should not be used on babies or children.
- treat your child (see further information below).
- use it for psoriasis. Topical corticosteroids can be effective in psoriasis in the short term. The condition may relapse or significantly worsen on stopping treatment and there is a risk of widespread pustular psoriasis. This is a condition where the psoriasis spreads and becomes very inflamed. In order to minimise side effects Locoid Ointment should only be used on small areas of psoriasis (e.g. scalp, hands and feet). If your doctor has prescribed Locoid Ointment to treat psoriasis, you should let your doctor review your progress regularly as such treatment needs careful supervision.
- use it on an area where you have previously had a skin infection

During treatment:

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

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. In infants treatment should be limited to a maximum of seven days. Bandages and dressings should not be used on babies or children.

Other medicines and Locoid Ointment

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 Locoid Ointment if you are pregnant or breast-feeding unless clearly necessary. There may be a small risk of harm to your baby if you use any corticosteroid ointment whilst pregnant, so if your doctor does prescribe it for you knowing you are pregnant, you should not use it in large amounts for a long time.

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

Locoid Ointment is unlikely to affect your ability to drive or use machines.

3. How to use Locoid® Ointment

Always use this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure. If your skin problem does not improve, you should go back to your doctor.

The recommended dose of Locoid Ointment is no more than twice daily. Thickened areas of psoriasis on elbows and knees may be treated with Locoid Ointment under a dressing, but only if your doctor has told you so.

This medicine is for cutaneous use. Apply a thin layer of Locoid Ointment to the affected skin. Gently massage the ointment into the affected area.

On advice of your doctor you may have to apply Locoid Ointment under an airtight dressing in order to obtain a better result.

Unless you are using Locoid to treat your hands, always wash your hands after using Locoid Ointment.

If you use more Locoid Ointment than you should

If you have used too much Locoid Ointment the side effects (as described in Section 4) can occur. Contact your doctor, pharmacist or nurse immediately.

If you forget to use Locoid Ointment

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

If you stop using Locoid Ointment

The original symptoms may return if you stop using Locoid Ointment prematurely. 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.

A small number of people may be hypersensitive (allergic) to the constituents of Locoid Ointment. If your skin condition seems to get worse, the skin becomes red, itchy or irritated, tell your doctor, pharmacist or nurse if this becomes troublesome.

If Locoid Ointment is used in moist skin areas (e.g. skin folds) the skin may become thin and damaged. Tell your doctor if this happens.

Locoid Ointment may cause the following:

Rare side effects (may affect up to 1 in 1,000 people)

- Thinning of the skin (atrophy)
- Inflammation of the skin (dermatitis)
- Bruising
- Stretch marks
- Facial spots (acne)
- Redness of the skin around the mouth (perioral dermatitis)
- Worsening of the skin condition after treatment has stopped
- Discolouration of skin

Very rare side effects (may affect up to 1 in 10,000 people)

- Suppression of the release of the stress hormones

Frequency not known (cannot be estimated from the available data)

- Allergic reaction (hypersensitivity)
- Blurred vision
- Itching (pruritus)
- Redness of the skin (erythema)
- Rash
- Application site pain

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 Locoid® Ointment

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 refrigerate or freeze.

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 Locoid Ointment contains

- The active substance is hydrocortisone butyrate. Locoid Ointment contains 0.1% hydrocortisone butyrate.
- The other ingredients are liquid paraffin and polyethylene.

What Locoid Ointment looks like and contents of the pack

Locoid Ointment is a light grey to white ointment and is available in 30 g, 50 g, 100 g or 200 g tubes with white polyethylene screw caps. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:

LEO Pharma A/S, Industriparken 55, DK-2750 Ballerup, Denmark

Manufacturer:

Temmler Italia S.r.l.,
Via Delle Industrie 2, 20061, Carugate (MI), Italy

Further support and information for skin conditions such as eczema can be gained from:

National Eczema Society

11 Murray Street, London

NW1 9RE, UK.

Helpline Tel: 0800 089 1122

This leaflet was last revised in January 2021.

For information in large print, Braille or audio/CD, telephone +44 (0)1844 347333