

Locoid® Ointment 0.1% w/w

Hydrocortisone butyrate

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 or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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

The active substance in Locoid Ointment (hydrocortisone butyrate) 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 used to treat a variety of skin conditions that respond to topical corticosteroids. 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** (hypersensitive) to hydrocortisone butyrate or any of the other ingredients of Locoid Ointment. See section 6 "Contents of the pack and other information" for a list of other ingredients.
- 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.
- you have skin problems associated with **syphilis (a sexually transmitted disease) or tuberculosis**.
- the **skin around your mouth is inflamed (perioral dermatitis)**. It might be the result of previous treatment with corticosteroids.
- you have **pimples or spots (acne)**.
- you have **redness of the facial skin**.

Warning and precautions

Take special care with Locoid Ointment 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. Do not apply to the eyelids in the view of the risk of glaucoma or cataract.
- 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. In infants, Locoid Ointment should not normally be used for more than seven days.
- 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.

Other medicines and Locoid Ointment

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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

3. How to use Locoid® Ointment

Instructions for proper use

Apply a thin layer of Locoid Ointment to the affected skin.

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

Dosage

Always use Locoid Ointment exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. If your skin problem does not improve, you should go back to your doctor.

The usual dose of Locoid Ointment is two or three times 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.

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 or pharmacist 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 or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone 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 or pharmacist 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, redness of the skin, bruising and stretch marks
- Facial spots, redness of the skin around the mouth
- 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.

The signs and symptoms of stress hormone suppression include weight loss, darkening of the skin and vomiting, irritability, depression, dehydration, low blood pressure, muscle fatigue and weakness as well as muscle or joint pain and diarrhoea.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin2; Tel +353 1 6764971; Fax +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Locoid® Ointment

Locoid Ointment should be stored in the original packaging and not above 25°C.

Keep out of the sight and reach of children.

Do not use Locoid Ointment after the expiry date which is stated on the tube or carton after EXP.

The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Locoid Ointment contains

- The active substance is hydrocortisone butyrate. Locoid Ointment contains 0.1% w/w hydrocortisone butyrate.
- The other ingredients are polyethylene oleogel (liquid paraffin, polyethylene).

What Locoid Ointment looks like and contents of the pack

Locoid Ointment is a light grey to white ointment and is supplied in 30 or 100 gram tubes with white polyethylene screw caps.

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
or
Astellas Pharma Europe B.V., Sylviusweg 62, 2333 BE Leiden, Netherlands

This leaflet was last revised in November 2016

