

Locoid® Cream

145716

Hydrocortisone butyrate 0.1% w/w

Read all of this leaflet carefully before you start using this medicine.

- 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 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.

In this leaflet:

1. What Locoid Cream is and what it is used for
2. Before you use Locoid Cream
3. How to use Locoid Cream
4. Possible side effects
5. How to store Locoid Cream
6. Further information

1. WHAT LOCOID CREAM IS AND WHAT IT IS USED FOR

The active substance in Locoid Cream (hydrocortisone butyrate) is a corticosteroid which when made up as a cream 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 Cream 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 Cream 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 Cream prematurely.

2. BEFORE YOU USE LOCOID CREAM

Do not use Locoid Cream if:

- you are **allergic** (hypersensitive) to hydrocortisone butyrate or any of the other ingredients of Locoid Cream. See section 6 "Further Information" for a list of other ingredients and see also the end of this section for some important information on some of the 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 Cream 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**.

Take special care with Locoid Cream 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 Cream at skin folds, under an airtight dressing or on large areas of your skin. If you are using Locoid Cream 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 Cream 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 Cream should only be used on small areas of psoriasis (e.g. scalp, hands and feet). If your doctor has prescribed Locoid Cream to treat psoriasis, you should let your doctor review your progress regularly as such treatment needs careful supervision.

Taking other medicines

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 Cream if you are pregnant or breastfeeding unless clearly necessary. There may be a small risk of harm to your baby if you use any corticosteroid cream 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 Cream is unlikely to affect your ability to drive or use machines.

Important information about some of the ingredients of Locoid Cream

Locoid Cream contains cetostearyl alcohol that may cause local skin reactions (e.g. contact dermatitis) and propyl parahydroxybenzoate (E216) and butyl parahydroxybenzoate (E218) that may cause allergic reactions (possibly delayed).

3. HOW TO USE LOCOID CREAM

Instructions for proper use

Apply a thin layer of Locoid Cream to the affected skin. Gently massage the cream into the affected area.

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

Dosage

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

If you use more Locoid Cream than you should

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

If you forget to use Locoid Cream

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

If you stop using Locoid Cream

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

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

4. POSSIBLE SIDE EFFECTS

A small number of people may be hypersensitive (allergic) to the constituents of Locoid Cream. 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 Cream is used in moist skin areas (e.g. skin folds) the skin may become thin and damaged. Tell your doctor if this happens.

Like all medicines, Locoid Cream can cause side effects, although not everybody gets them.

Locoid Cream may cause the following:

Rare side effects (likely to affect more than 1 in 10,000 patients and less than 1 in 1000 patients)

- 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 (likely to affect less than 1 in 10,000 patients)

- Suppression of the release of the stress hormones.

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

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LOCOID CREAM

Locoid Cream should be stored in the original packaging and not above 25°C. Do not refrigerate or freeze.

Keep out of the reach and sight of children.

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

6. FURTHER INFORMATION

What Locoid Cream contains

- The active substance is hydrocortisone butyrate. Locoid Cream contains 0.1% hydrocortisone butyrate.
- The other ingredients are cetostearyl alcohol, macrogol 25 cetostearyl ether, liquid paraffin, white soft paraffin, propyl parahydroxybenzoate (E216), butyl parahydroxybenzoate (E218), citric acid (E330), sodium citrate (E331) and purified water.

What Locoid Cream looks like and contents of the pack

Locoid Cream is a white cream and is supplied in 30 or 100 gram tubes with white polyethylene screw caps.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:

Astellas Pharma Ltd.,
2000 Hillswood Drive, Chertsey, Surrey, KT16 0RS, UK.

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
Hill House, Highgate Hill, London, N19 5NA, UK
Information Centre Tel: 0870 2413604

This leaflet was last approved in January 2015.