

Package Leaflet: Information for the user

Locoid[®] Cream 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 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Locoid[®] Cream is and what it is used for
2. What you need to know before you use Locoid[®] Cream
3. How to use Locoid[®] Cream
4. Possible side effects
5. How to store Locoid[®] Cream
6. Contents of the pack and other 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 indicated in adults, children and infants above 3 months of age. It is used to treat a variety of skin conditions which are 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 Cream prematurely.

2. What you need to know 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 "Contents of the pack and other 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**.

Warnings and precautions

Talk to your doctor before using Locoid Cream. 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. Do not apply to the eyelids in view of the risk of glaucoma or cataract.
- 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.
- treat your child (see further information below under the heading "Children and adolescents").
- 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.

During treatment:

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

Children and adolescents

In infants, Locoid Cream should not normally be used for more than seven days. Do not apply Locoid Cream under bandages or dressings in babies or children.

Other medicines and Locoid Cream

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 Cream 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 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.

Locoid Cream contains cetostearyl alcohol, propyl parahydroxybenzoate and butyl parahydroxybenzoate.

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

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 one or two times 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.

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.

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

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

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 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.

Locoid Cream 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 and 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.
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.

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

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

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 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 HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Locoid® Cream

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

Locoid Cream should be stored in the original packaging. Do not store above 25°C.

Do not refrigerate or freeze.

Do not use Locoid Cream 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.

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 Cream contains

- The active substance is hydrocortisone butyrate. Each gram of Locoid Cream contains 1 mg of hydrocortisone butyrate.
- The other ingredients are cetostearyl alcohol, macrogol cetostearyl ether, light liquid paraffin, white soft paraffin, propyl parahydroxybenzoate (E216), butyl parahydroxybenzoate (E218), citric acid anhydrous (E330), sodium citrate anhydrous (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:

CHEPLAPHARM Arzneimittel GmbH, Ziegelhof 24, 17489 Greifswald, Germany

Manufacturer:

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

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