

PACKAGE LEAFLET: INFORMATION FOR THE USER

Locoid Lipocream 0.1% cream

Hydrocortisone butyrate

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 get 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 Lipocream is and what it is used for
2. Before you use Locoid Lipocream
3. How to use Locoid Lipocream
4. Possible adverse reactions
5. How to store Locoid Lipocream
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1. WHAT LOCOID LIPOCREAM IS AND WHAT IT IS USED FOR

Locoid Lipocream contains a hormone of the adrenal cortex (corticosteroid) and quickly reduces the symptoms of some skin diseases – itching, redness, skin scaling.

Corticosteroids do not treat the main disease.

The base of the cream is applied in skin diseases in order to reduce the moisture.

Locoid Lipocream may be used for treatment of superficial skin conditions (not caused by microorganisms), accompanied with itching, redness or skin scaling.

Locoid Lipocream contains more oil than an usual cream and this makes it especially suitable in skin diseases of dry or mixed skin — partially dry and partially moisturized skin.

2. BEFORE YOU USE LOCOID LIPOCREAM

Do not use Locoid Lipocream

- If you have skin diseases, caused by infections, which derive from bacteria, viruses, fungi, yeast or parasites. These diseases may get complicated or be masked.
- If you have acne, as well as skin redness.
- If you have wounds or ichthyosis.
- If you have skin diseases which may be a result of previous treatment with corticosteroids as skin inflammation around mouth, skin thinning, possibly with striae, fragile blood vessels.
- In case of rash in children with sores of walking feet.
- If you are allergic (hypersensitive) to hydrocortisone butyrate or some of the other Locoid Lipocream ingredients (which occurs rarely). See also Section 'Important Information' Regarding Some Locoid Lipocream Ingredients'.

Take special care with the use of Locoid Lipocream

1. Facial skin and skin in genital area, as well as skin in folds is especially sensitive to corticosteroids. That is why it should be treated with care.
2. If you apply Locoid Lipocream under occlusive dressing or bandage or on a large skin area or in children, a physician examination is necessary.
3. Locoid Lipocream should not get into the eyes and should not be applied on eyelids.
4. Continuous corticosteroid use on a large skin area should be avoided in children.

Consult your doctor if some of the above mentioned warnings concern you.

If after continuous treatment with Locoid Lipocream the disease returns after a short time, you should consult your doctor.

Use of other drugs

Please, note: The following remarks may also refer to the use of drugs in the near past or near future. Please, inform your doctor or pharmacist if you take or have recently taken other drugs, including OTC drugs.

Pregnancy and Lactation

Pregnancy:

The use of high doses of corticosteroids may lead to retardation of the foetus growth. As only a small quantity of the active substance is available in blood during the use of

Locoid Lipocream, it may be used also for a short time on small skin areas. The above described effect cannot be excluded in continuous treatment or in application on larger skin areas.

Ask your doctor or pharmacist for an advice before the use of any drug. If you want to use Locoid Lipocream during pregnancy you should consult first your doctor.

Lactation:

Locoid Lipocream may be used by women who breast-feed in case of short-term treatment and the product is applied on small areas. In continuous treatment or in treating of large skin areas breast-feeding is not recommended.

Ask your doctor or pharmacist for an advice before use of any drug. If you want to use Locoid Lipocream during breast-feeding you should consult first your doctor.

Effects on ability to drive and use machines

There is no data for the effect of Locoid Lipocream on the ability to drive and use machines, but such an effect is not expected.

Important information regarding some Locoid Lipocream ingredients

Cetostearyl alcohol may provoke local skin reactions (e.g. contact dermatitis).
Propyl parahydroxibenzoate (E 216) may provoke allergic reactions (possibly delayed).

3. HOW TO USE LOCOID LIPOCREAM

Locoid Lipocream should be applied in a thin layer on the affected skin. After that it may be massaged carefully. It should not be applied more than 1 to 3 times daily, if your doctor has not prescribed other.

If complaints reduce, your doctor may advise you to use Locoid Lipocream rarely. Usually you should not use more than 1-2 tubes of 30 g Locoid Lipocream a week.

If you have used more Locoid Lipocream than you should

If you have used more than the necessary dose of Locoid Lipocream, adverse reactions (as described in Section 4 'Possible adverse reactions') can occur. In this case contact your doctor or pharmacist immediately.

If you have missed to use Locoid Lipocream

Once you have forgotten to apply Locoid Lipocream, continue using Locoid Lipocream as usual. No need to apply higher quantity of Locoid Lipocream.

If you have stopped using Locoid Lipocream

If Locoid Lipocream treatment is discontinued too early, primary symptoms may return. Always consult your doctor if you intend to stop treatment.

4. POSSIBLE ADVERSE REACTIONS

Like all medicines Locoid Lipocream may cause adverse reactions, although not everybody gets them.

During Locoid Lipocream application the following adverse reactions may occur:

Immune system disorders

Very rare (in less than 1 in 10 000 patients)

- hypersensitivity

Metabolic system disorders

Rare (in more than 1 in 10,000, but less than 1 in 1,000 patients)

- adreno-cortical suppression (suppression of the adrenal gland)

In case of continuous treatment with corticosteroids applied on the skin, they may penetrate through the skin and reach blood. This may lead to adreno-cortical suppression. There is a higher risk of systemic adverse reactions in case of:

- application under occlusive dressing (under occlusion, in skin folders)
- application on large skin areas
- continuous treatment
- application in children

Eyes disorders

Very rare (in less than 1 in 10 000 patients)

Increased intra-ocular pressure with increased risk of cataract.

Skin and subcutaneous tissue disorders

Rare (in more than 1 in 10,000, but less than 1 in 1,000 patients)

- burning or itching sensation of the treated with Locoid Lipocream skin. Usually this is not serious and disappears by itself.

- skin discoloration and thinning (often irreversible), sometimes with striae, skin blood vessels dilatation, excessive hairiness (hypertrichosis).

- worsening of a skin disease after discontinuation of the treatment ('rebound effect').
- itching, pimples or purulence if you have used continuously Locoid Lipocream under occlusive dressing.
- ekzema or skin inflammation (dermatitis), including skin inflammation as a result of a contact with irritating substances or substances provoking hypersensitivity (contact dermatitis).

If any of the adverse drug reactions gets serious, or if you notice any other reactions, not listed in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE LOCOID LIPOCREAM

Keep out of the reach and sight of children
Stored under 25° C. Do not store in a refrigerator or freezer.

Locoid Lipocream should not be used after the expiry date, mentioned on the tube and the carton package. The expiry date refers to the last day of the mentioned month.

Drugs should not be thrown in wastewater or in household waste container. Ask your pharmacist how to destroy the drugs you no longer use. These measures will help to protect the environment.

6. FURTHER INFORMATION

What does Locoid Lipocream contain

The active substance is hydrocortisone butyrate.
1 g of the cream Locoid Lipocream contains the active substance *hydrocortisone butyrate* 1 mg.

Other ingredients are: cetostearyl alcohol, macrogol cetostearylether, light liquid paraffin, white soft paraffin, propyl parahydroxybenzoate E216, benzyl alcohol, citric acid, anhydrous 330, sodium citrate, anhydrous E331, purified water

in, borage, refined oil, butylhydroxytoluene E321, propyleneglycol, E1520, sodium citrate, anhydrous E331, citric acid, anhydrous E330, butyl parahydroxybenzoate E218, purified water.

How Locoid Lipocream looks like and what the package contains

Locoid Lipocream has white color. It is in tubes of 15 g or 30 g. Tubes are packed in a yellow/grey/white carton box with a printed name Locoid Lipocream 0.1%.

Not all packages can be marketed.

Marketing Authorization Holder:

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

Manufacturers:

Astellas Pharma Europe B.V.
Sylviusweg 62
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and

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