Consumer Medicine Information

LOCOID[®]

0.1% Hydrocortisone butyrate

<u>Formulations</u> Lipocream Ointment Topical Emulsion (Locoid Crelo[®]) Scalp Lotion

What is in this leaflet

This leaflet answers some common questions about Locoid[®]. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the expected benefits.

Use $\mathsf{Locoid}^{\circledast}$ as instructed. If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet. You may need to read it again.

What Locoid[®] is used for

Locoid[®] is used on the skin in adults and children to relieve the redness, swelling, itching and discomfort of skin inflammation such as:

- Psoriasis (a skin disorder with raised, rough, reddened areas covered with dry, fine silvery scales)
- Eczema (a skin condition with itching, redness and a burning feeling. In some forms of eczema there may be oozing sores that become hard and scaly)
- Other types of dermatitis (itching skin diseases)

Hydrocortisone butyrate belongs to a group of medicines called corticosteroids.

Your doctor may have prescribed Locoid[®] for another reason. Ask your doctor why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you use Locoid®

When you must not use Locoid®

Do not use this medicine if you have:

- 1. an allergy to:
 - any medicine containing hydrocortisone butyrate

• any of the ingredients listed at the end of this leaflet (see Product Description). Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

- 2. skin lesions caused by:
 - any bacterial infection (such as impetigo, tuberculosis)
 - any viral infection (such as cold sores, shingles, chicken pox, common warts, flat warts, anogenital warts, or the skin lesions, called "molluscacontagiosa")
 - any fungal skin infection (such as thrush, tinea orringworm)
 - parasitic infection (such as scabies)
- 3. skin ulcer(s) or wound(s)
- 4. experienced side effects caused by other corticosteroids (such as dermatitis around the mouth or stretch marks anywhere)
- 5. any of the following skin problems:
 - Ichthyosis (rough, fish-scale like skin)
 - Juvenile plantar dermatosis (a skin problem on the feet of children)
 - Common acne or rosacea
 - fragile blood vessels
 - thinning of the skin

Talk to your doctor or pharmacist if you are concerned you may have any of these conditions.

Do not use this medicine just before having a bath, shower or going swimming. If you do, you may reduce the effectiveness of Locoid^{®.}

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use Locoid®

Tell your doctor if:

- 1. you have any skin disorders (other than psoriasis, eczema or dermatitis) or skin infections
- 2. you have a known allergy to Locoid[®] or any ingredients listed at the end of this leaflet
- 3. you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes
- 4. you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start using this medicine.

There is no evidence that this medicine is addictive.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may interfere with Locoid[®].

These medicines may be affected by Locoid[®] or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use Locoid®

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to use

Locoid[®] should be applied to the affected parts 1 to 4 times daily, or as directed by your doctor.

When to use Locoid®

Use your medicine at about the same time each day. Using it at the same time each day will have the best effect. It will also help you remember when to use it.

How to use Locoid®

Locoid[®] is to be applied to the skin.

It is important to use Locoid[®] exactly as your doctor or pharmacist has told you. If you use it less often than you should, it may not work as well and your skin problem may not improve. Using it more often than you should may not improve your skin problem any faster and may cause or increase side effects.

If you have accidentally applied too much of the cream, wipe off the excess with clean paper tissue.

How long to use Locoid®

Follow carefully all directions given to you by your doctor and the pharmacist. These directions may differ from the information contained in this leaflet.

Do not use this medicine for longer than your doctor tells you. If you use this medicine for longer than your doctor or pharmacist tells you, the chance of side effects may increase.

It is recommended that babies and children up to four years of age should not be treated with Locoid $^{\mbox{\tiny @}}$ for longer than 3 weeks.

If you are unsure how long to use Locoid[®], ask your doctor or pharmacist for help.

If you forget to use Locoid®

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Otherwise, use it as soon as you remember, and then go back to using your medicine as you would normally.

Do not use a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your doctor or pharmacist for some hints.

While you are using Locoid®

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using this medicine.

If you feel that this medicine is not helping your condition, tell your doctor.

Tell your doctor if, for any reason, you have not used this medicine exactly as **prescribed.** Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

If you become pregnant while using this medicine, tell your doctor immediately.

Things you must not do

Do not use this medicine under dressings or on large areas of skin unless your doctor tells you.

Do not use this medicine in or near the eyes.

Do not use this medicine to treat any other complaints unless your doctor tells you to. Do not

give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Do not use large amounts of this medicine for a long time. If you use large amounts for a long time, the chance of side effects increases.

Do not use this medicine for prolonged treatment on the face, or in the skin folds such as under the arm, front of elbows, back of knees, the groin area, and anal or genital areas unless your doctor tells you to.

Side effects are more likely to develop if Locoid[®] is used under a dressing or in the skin folds.

In infants the napkin may act as a dressing that results in increased uptake of Locoid®.

The skin on the face, skin areas where hair grows and the skin of the genitals are particularly sensitive to the action of $Locoid^{\otimes}$.

In children the application of topical steroids, such as Locoid[®], should be limited as much as possible.

Ask your doctor or pharmacist if you are concerned about the length of time you have been using this medicine.

Locoid Crelo® emulsion and Locoid® Lipocream contain the ingredient parabens. Parabens may

cause delayed hypersensitivity in some individuals.

Side-Effects

Like all medicines, Locoid[®] can cause some side effects. Side effects not listed in this leaflet may occur in some patients.

Tell your doctor or pharmacist if you have any unpleasant effects while you are using Locoid[®] even if you do not think the effect is connected with the medicine or is not listed in this leaflet.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor as soon as possible if you notice any of the following effects on the skin, where you apply the medicine:

- burning, itching or irritation of the skin at the site. This may be due to a "contact allergy"
- thinning, discolouration or loss of pigment
- reddening or rash
- flare –up of the original skin problem when you stop the medicine. This is known as a "rebound effect". It may make it difficult to stop the medicine abruptly.

Incorrectly diagnosed bacterial, parasitic, fungal or viral infection may be masked and/or aggravated.

Tell your doctor as soon as possible if you notice any of the following general effects

- delay of wound healing
- eye problems: for example, increased eye pressure may not cause symptoms but shows on testing; cataract(s) may decrease vision.
- increased body hair
- change in body weight, fat distribution or general health. These may be signs of imbalance of adrenal gland hormones. This rarely occurs in adults, but is serious.
- symptoms of an allergic reaction, such as a generalised rash or swelling.

The above list includes serious side effects, usually caused by continued use on large areas of skin. Serious side effects are rare, however they require medical attention.

The risk of such side effects is highest when:

- the treated area is covered with a dressing or in a skin fold
- Locoid[®] is applied on large surfaces
- long-term treatment occurs
- application occurs in children
- the presence of components which increase penetration through the skin or increase the effect of Locoid[®].

Tell your doctor or pharmacist if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some people.

In case of Overdose

If you swallow Locoid®

Immediately telephone your doctor or the Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that

you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

After using Locoid®

Keep Locoid[®] in pack until required.

Storage

Store Locoid[®] in a cool dry place below 25°C.

Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep Locoid[®] where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not use Locoid[®] after the expiry date on the package.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What Locoid® looks like

Locoid® Lipocream is a white or nearly white cream

Locoid® Ointment is a white ointment

Locoid Crelo® Topical Emulsion is a practically white emulsion

Locoid® Scalp Lotion is a clear, colourless solution

Pack sizes

Locoid[®] Lipocream is available as 30 g or 100 g pack. Locoid[®] Ointment is available as a 100 g pack. Locoid Crelo[®] Topical Emulsion is available as a 100 mL pack. Locoid[®] Scalp Lotion is available as a 100 mL pack.

Ingredients

Active ingredients:

Locoid® contains 1mg/g of hydrocortisone butyrate as the active ingredient.

Inactive ingredients:

Locoid[®] Lipocream also contains:

- cetostearyl alcohol
- macrogol (25) cetostearyl ether
- light liquid paraffin
- white soft paraffin
- citric acid (anhydrous)
- purified water
- sodium citrate (anhydrous)

- propyl parahydroxybenzoate
- benzyl alcohol

Locoid[®] Ointment also contains:

• Polyethylene oleogel (liquid paraffin gel, polyethylene)

Locoid Crelo[®] Topical Emulsion also contains:

- cetostearyl alcohol
- macrogol (25) cetostearyl ether
- hard paraffin
- white soft paraffin
- citric acid (anhydrous)
- borage oil
- butylated hydroxytoluene
- propylene glycol
- sodium citrate (anhydrous)
- propyl parahydroxybenzoate
- butyl parahydroxybenzoate
- purified water

Locoid[®] Scalp Lotion also contains:

- isopropyl alcohol
- glycerol
- povidone (K90)
- citric acid (anhydrous)
- sodium citrate (anhydrous)
- purified water

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

This is not all the information available on Locoid[®]. If you have any more questions or are unsure about anything, ask your doctor or pharmacist.

Supplier

Locoid[®] is supplied in New Zealand by:

Link Pharmaceuticals Ltd. Suite 38, Level 8 139 Quay Street Auckland 1010 Telephone: +64 (9) 358 7146

This leaflet was prepared in February 2024.

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