

Locoid® Scalp Lotion 0.1% w/v

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® Scalp Lotion is and what it is used for
2. What you need to know before you use Locoid® Scalp Lotion
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6. Contents of the pack and other information

1. What Locoid® Scalp Lotion is and what it is used for

The active substance in Locoid Scalp Lotion (hydrocortisone butyrate) is a corticosteroid which when made up as a lotion 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 Scalp Lotion 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 Scalp Lotion is used to treat a variety of skin conditions such as eczema and dermatitis (itching) of all types, but it is used in particular in the treatment of psoriasis of the scalp. This is a condition resulting in thickening of areas of the scalp. It can also be used for the treatment of seborrhoea capitis, a condition causing redness and inflammation of the scalp, and scaling of the scalp with crusted patches, often with severe dandruff. It is not suitable for treating large areas of psoriasis of the scalp. You should let your doctor review your progress regularly as treatment of psoriasis needs careful supervision. The original symptoms may return if you stop using Locoid Scalp Lotion prematurely.

2. What you need to know before you use Locoid® Scalp Lotion

Do not use Locoid Scalp Lotion if:

- you are **allergic** (hypersensitive) to hydrocortisone butyrate or any of the other ingredients of Locoid Scalp Lotion. 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 Scalp Lotion 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**.
- treating areas other than the scalp.

Warnings and precautions

Take special care with Locoid Scalp Lotion if you intend to:

- use Locoid Scalp Lotion under an airtight dressing or on small areas of the scalp.
- use Locoid Scalp Lotion under bandages, it should only be on small areas for a short time and only on the advice of your doctor.
- treat your child. In infants, Locoid Scalp Lotion 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 Scalp Lotion should only be used on small areas of psoriasis. If your doctor has prescribed Locoid Scalp Lotion to treat psoriasis, you should let your doctor review your progress regularly as such treatment needs careful supervision.

Bandages and dressings should not be used on babies or children.

Other medicines and Locoid Scalp Lotion

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 Scalp Lotion 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 lotion 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 Scalp Lotion is unlikely to affect your ability to drive or use machines.

3. How to use Locoid® Scalp Lotion

Instructions for proper use

Apply a thin layer of Locoid Scalp Lotion to the affected scalp.

Dosage

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

The usual dose of Locoid Scalp Lotion is two or three times daily. Do not use Locoid Scalp Lotion near a naked flame.

If you use more Locoid Scalp Lotion than you should

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

If you forget to use Locoid Scalp Lotion

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

If you stop using Locoid Scalp Lotion

The original symptoms may return if you stop using Locoid Scalp Lotion 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 Scalp Lotion. 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 Scalp Lotion is used in moist skin areas (e.g. skin folds) the skin may become thin and damaged. Tell your doctor if this happens.

Locoid Scalp Lotion 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 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, 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® Scalp Lotion

Do not store Locoid Scalp Lotion above 25°C.

Keep out of the sight and reach of children.

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

6. Contents of the pack and other information

What Locoid Scalp Lotion contains

- The active substance is hydrocortisone butyrate. Locoid Scalp Lotion contains 0.1% w/v hydrocortisone butyrate.
- The other ingredients are isopropyl alcohol, glycerol 85%, povidone K90, anhydrous sodium citrate, anhydrous citric acid and purified water.

What Locoid Scalp Lotion looks like and contents of the pack

Locoid Scalp Lotion is a clear, colourless to faintly yellow solution and is supplied in 30 or 100 ml plastic squeeze bottles.

Not all pack sizes may be marketed.

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

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