

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Locoid Cream 0.1 % w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The cream contains Hydrocortisone butyrate 0.1 % w/w.

Excipients: also includes cetostearyl alcohol 7.2% w/w; propyl parahydroxybenzoate (E216) 0.1% w/w and butyl parahydroxybenzoate 0.05% w/w.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.
A white aqueous-based cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

The product is recommended for clinical use in the treatment of conditions responsive to topical corticosteroids e.g. eczema, dermatitis and psoriasis not caused by micro-organisms.

Topical corticosteroids are not generally indicated in psoriasis but may be acceptable in psoriasis excluding widespread plaque psoriasis provided warnings are given, see section 4.4 Special warnings and special precautions for use.

4.2 Posology and method of administration

For topical application.

Dosage: to be applied evenly and sparingly one to three times daily.

Application may be made under occlusion in the more resistant lesions such as thickened psoriatic plaques on elbows and knees. Overnight occlusion is usually sufficient to give a satisfactory response.

Adults and older people: the same dose is used for adults and older people, as clinical evidence would indicate that no special dosage regimen is necessary in older people.

Children and infants: long term treatment should be avoided and occlusion should not be used. Courses should be limited to seven days where possible.

4.3 Contraindications

Hypersensitivity to hydrocortisone or to any of the excipients listed in section 6.1.

This preparation is contraindicated in the presence of untreated viral or fungal infections (mycotic yeast) or parasitic infections, tubercular or syphilitic lesions ulcerous skin lesions, peri-oral dermatitis, acne vulgaris and rosacea and in bacterial infections unless used in connection with appropriate chemotherapy.

4.4 Special warnings and precautions for use

Although generally regarded as safe, even for long-term administration in adults, there is a potential for adverse effects if over used in infancy. Extreme caution is required in dermatoses of infancy including napkin eruption. In such patients courses of treatment should not normally exceed 7 days.

Application under occlusion should be restricted to dermatoses involving limited areas.

As with all corticosteroids, application to the face, flexures and other areas of thin skin may cause skin atrophy and increased absorption and should be avoided. Such areas should only be treated with corticosteroids of low potency. Absorption of corticosteroids can be greatly increased when applied to large areas in particular to skin folds and under (plastic) occlusion, leading to suppression of adrenal cortex function. This can occur quite quickly in children and can lead to suppression of growth hormone secretion

Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapse following development of tolerance, risk of generalised pustular psoriasis and local and systemic toxicity due to impaired barrier function of the skin. Steroids may have a place in psoriasis of the scalp and chronic plaque psoriasis of the hands and feet. Careful patient supervision is important.

Do not apply to the eyelids in view of the risk of glaucoma simplex or subcapsular cataract. Keep away from the eyes.

The cetostearyl alcohol may cause local skin reactions (e.g contact dermatitis) and the butyl and propyl parahydroxybenzoate may cause allergic reactions which can be delayed.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Corticosteroids pass the placenta and may therefore influence the foetus. This is only of significance when large areas are treated intensively with corticosteroids of high potency. There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in the human foetus. Theoretically, there is the possibility that if maternal systemic absorption occurred the infant's adrenal function could be affected.

The safety of topical corticosteroids during lactation has not been established. The potential benefit of topical corticosteroids, if used during lactation, should be weighed against possible hazard to the nursing infant.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

The following adverse drug reactions were reported:

<u>System Organ Class</u>	<u>Rare >1/10,000<1/1000</u>	<u>Very Rare <1/10,000</u>	<u>Not known cannot be estimated from the available data</u>
<u>Immune system disorders</u>			<u>Hypersensitivity</u>
<u>Endocrine disorders</u>		<u>Adrenal suppression</u>	
<u>Skin and subcutaneous tissue disorders</u>	<u>Skin atrophy, often irreversible, with thinning of the epidermis</u> <u>Telangiectasia</u> <u>Purpura</u> <u>Skin striae</u> <u>Pustular acne</u> <u>Perioral dermatitis</u> <u>Rebound effect</u> <u>Skin depigmentation</u> <u>Dermatitis and eczema including contact dermatitis</u>		

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

4.9 Overdose

Excessive use, especially under occlusive dressings or over a long period of time, may produce adrenal suppression. No special procedures or antidote. Treat any adverse effects symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Moderately potent corticosteroids (group 2) ATC: D07AB

Mechanism of action

The active principal of Locoid is the synthetic corticosteroid hydrocortisone 17 – butyrate. It has a rapid anti-inflammatory and vasoconstrictive action. It suppresses the inflammatory reaction while in use and reduces the symptoms of a number of disorders that are often accompanied by pruritus. The underlying condition is not cured.

The effect of corticosteroids may be increased by application of an occlusive dressing that increases penetration of the stratum corneum by a factor of around 10.

5.2 Pharmacokinetic properties

Hydrocortisone 17-butyrate penetrates the skin. Occlusion enhances penetration. It is bound to plasma proteins and is hydrolysed to hydrocortisone in plasma and by the liver. Small amounts of hydrocortisone butyrate are excreted in the urine and with the faeces. In-vivo studies have demonstrated the topical activity of the product, e.g. by the McKenzie-Stoughton test.

5.3 Preclinical safety data

No relevant pre-clinical safety data has been generated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol cetostearyl ether
Cetostearyl alcohol
White soft paraffin
Light liquid paraffin
Sodium citrate anhydrous
Anhydrous Citric acid
Propyl parahydroxybenzoate (E216)
Butyl parahydroxybenzoate
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate or freeze.

6.5 Nature and contents of container

Aluminium tube with plastic cap containing 30g or 100g.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA1025/006/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14 October 1977

Date of last renewal: 14 October 2007

10 DATE OF REVISION OF THE TEXT

October 2016