Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Locoid Cream 0.1 % w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 gram of cream contains 1 mg of hydrocortisone butyrate.
Excipient(s) with known effect:
Cetostearyl alcohol 7.2% w/w; propyl parahydroxybenzoate (E216) 0.1% w/w and butyl parahydroxybenzoate (E218) 0.05% w/w.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.
White cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

The product is recommended for the treatment of inflammatory skin disorders not caused by micro-organisms e.g. eczema, dermatitis and psoriasis.
Locoid is indicated in adults, children and infants above 3 months of age.
Topical corticosteroids are 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 two 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, occlusion and prolonged treatment should be avoided. Courses should be limited to seven days.

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

Locoid should not be applied to the eyelids in view of the risk of glaucoma simplex or subcapsular cataract.

Keep away from the eyes.

Although generally regarded as safe, even for long-term administration in adults, there is a potential for adverse effects if over used in infancy. Whilst clinical studies have not demonstrated paediatric-specific problems that would limit the usefulness of topical hydrocortisone 17-butyrate in children, 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, genitals 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. Hands must be washed after each application unless Locoid is used to treat the hands.

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.

In some patients with psoriasis, topical corticosteroids may cause 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.

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Excipients
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 interactions

None known.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no or limited amount of data from the use of hydrocortisone 17-butyrate in pregnant women. Results from several observational studies (more than 1000 exposed pregnancy outcomes) have not revealed a significant association between topical corticosteroid use during pregnancy and congenital abnormalities, preterm delivery, fetal death, or mode of delivery, regardless of potency.
Animal studies are insufficient with respect to reproductive toxicity of hydrocortisone 17-butyrate (see section 5.3). Although, animal studies have shown the more potent corticosteroids to be teratogenic after dermal application, the clinical relevance in humans has not been established. Therefore, during pregnancy Locoid® should only be used when the potential benefit justifies the potential risk.
Lactation
It is unknown whether hydrocortisone 17-butyrate/metabolites are present in maternal milk following topical application.
The use of Locoid during breastfeeding is not expected to affect breastfed infants since the systemic absorption of topically applied hydrocortisone 17-butyrate is low.
Locoid® can be used during breastfeeding, but it is recommended to avoid applying Locoid® directly on the breast.
Fertility
No animal or human data on Locoid® and fertility is available

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

In clinical studies, cases of skin irritation and hypersensitivity were reported.
The most frequently reported adverse reactions post-marketing are hypersensitivity and skin reactions such as erythema, pruritus and skin infection.
Adverse reactions are listed by MedDRA System Organ Class.

Frequencies are defined as very rare (<1/10,000), rare (≥1/10,000 to <1/1,000), uncommon (≥1/1,000 to <1/100), common (≥ 1/100 to <1/10), very common (≥1/10), and not known (cannot be estimated from the available data). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

System Organ Class	Rare ›1/10,000‹1/1000	Very Rare ‹1/10,000	Not known (cannot be estimated from the available data)
Infections and infestations			Skin infection
Immune system disorders			Hypersensitivity
Endocrine disorders		Adrenal suppression	
Eye disorders			Vision, blurred*
Skin and subcutaneous tissue disorders	Skin atrophy** Dermatitis*** Telangiectasia Purpura Skin striae Acne Perioral dermatitis Skin depigmentation		Pruritus Erythema Rash
General disorders and administration site conditions	Rebound effect		Application site pain

*See also section 4.4

**Often irreversible, with thinning of the epidermis

***Dermatitis and eczema, including contact dermatitis have been reported.

Reporting of suspected adverse reactions

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, website: www.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 25 cetostearyl ether
Cetostearyl alcohol
White soft paraffin
Light liquid paraffin
Sodium citrate anhydrous (E331)
Anhydrous Citric acid (E330)
Propyl parahydroxybenzoate (E216)
Butyl parahydroxybenzoate (E218)
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

CHEPLAPHARM Arzneimittel GmbH
Ziegelhof 24
17489
Greifswald
Germany

8 MARKETING AUTHORISATION NUMBER

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

May 2021