SUMMARY OF PRODUCT CHARACTERISTICS

1  NAME OF THE MEDICINAL PRODUCT
Locoid Lipocream

2  QUALITATIVE AND QUANTITATIVE COMPOSITION
Locoid Lipocream contains 0.1% w/w hydrocortisone butyrate.

Excipient(s) with known effect:
Cetostearyl alcohol (6% w/w)
Propyl parahydroxybenzoate (E216) (0.05% w/w)

For the full list of excipients, see section 6.1

3  PHARMACEUTICAL FORM
Cream.

The product is a white cream with a high percentage (about 70%) of fats and oils.

4  CLINICAL PARTICULARS

4.1  Therapeutic indications
Locoid Lipocream is indicated in adults, children and infants. The product is recommended for clinical use in the treatment of conditions responsive to topical corticosteroids e.g. eczema, dermatitis and psoriasis.

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 precautions for use.

4.2  Posology and method of administration

Posology

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 the elderly.

**Paediatric population**
Long term treatment should be avoided where possible.

**Infants**
Therapy should be limited if possible to a maximum of seven days.

**Method of administration**

For cutaneous use.

Dosage: To be applied evenly and sparingly no more than twice daily
Application may be made under occlusion in the more resistant lesions such as thickened psoriatic plaques on elbows and knees.

Due to the formulation of the base the product may be used both for dry scaly lesions and for moist or weeping lesions.

### 4.3 Contraindications

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

This preparation is contraindicated in the presence of untreated viral or fungal infections, tubercular or syphilitic 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

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.

Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses 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.
The cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis) and the propyl parahydroxybenzoate (E216) may cause allergic reactions (possibly delayed).

Infants
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.

Keep away from the eyes.

4.5 Interaction with other medicinal products and other forms of interaction
No interaction studies have been performed.

4.6 Fertility, Pregnancy and lactation
Pregnancy
There are no or limited amount of data from the use of hydrocortisone butyrate in pregnant women. Studies in animal have shown reproductive toxicity (see section 5.3).

Breast-feeding
Hydrocortisone butyrate/metabolites are excreted in human milk, but at therapeutic doses of Locoid Lipocream no effects on the breast-fed newborns/infants are anticipated.

4.7 Effects on ability to drive and use machines
None known.

4.8 Undesirable effects
Tabulated list of adverse reactions

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Rare</th>
<th>Very rare</th>
<th>Not known</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&gt;1/10,000, &lt;1/1000</td>
<td>&lt;1/10,000</td>
<td>Hypersensitivity</td>
</tr>
<tr>
<td>Immune system disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endocrine disorders</td>
<td></td>
<td>Adrenal suppression</td>
<td></td>
</tr>
<tr>
<td>Skin and</td>
<td>Skin atrophy, often irreversible,</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
subcutaneous tissue disorders
with thinning of the epidermis
Telangiectasia
Skin striae
Pustular acne
Perioral dermatitis
Rebound effect
Skin depigmentation
Dermatitis and eczema, including contact dermatitis

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose
Excessive use under occlusive dressings may produce adrenal suppression. No special procedures or antidote. Treat any adverse effects symptomatically

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Corticosteroid, ATC code: D07AB02
The active substance, hydrocortisone butyrate, is an established topical corticosteroid, equi-efficacious with those corticosteroids classified as potent.

5.2 Pharmacokinetic properties
In human in-vivo studies the potency of this formulation has been shown to be of the same order as other topical corticosteroids classified as potent. The active substance metabolises to hydrocortisone and butyric acid.

5.3 Preclinical safety data
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.
6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Macrogol Cetostearyl ether
Cetostearyl alcohol
White soft paraffin
Light liquid paraffin
Sodium citrate anhydrous E331
Citric acid anhydrous E330
Propyl parahydroxybenzoate E216
Benzyl Alcohol
Purified water

6.2 Incompatibilities
None stated.

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
Collapsible aluminium tube with plastic screw cap containing 15 g, 30 g, 50 g or 100 g.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal
No special requirements.
7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

PL 05293/0012

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 03 May 1983
Date of latest renewal: 24 August 2010.

10 DATE OF REVISION OF THE TEXT

05/09/2016