IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PPA0465/177/001
Case No: 2054664

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

PCO Manufacturing Limited

Unit 10, Ashbourne Business Park, **Rath**, **Ashbourne**, **Co. Meath**, **Ireland**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Locoid 0.1 % w/w Cream

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **20/10/2008** until **09/11/2011**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Locoid 0.1% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The cream contains 0.1% w/w Hydrocortisone Butyrate
Excipients: Cetostearyl Alcohol
Propyl parahydroxybenzoate (E216)
Butyl parahydroxybenzoate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
Product imported from France:
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.
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 two or 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 the elderly: the same dose is used for adults and the elderly, as clinical evidence would indicate that no special dosage regimen is necessary in the elderly.

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 ingredients of the cream.
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

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.
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.
Keep away from the eyes.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

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

Local atrophic changes may occur, particularly in skin folds, intertriginous areas or in nappy areas in young children where moist conditions favour hydrocortisone absorption. Systemic absorption from such sites may be sufficient to produce hypercorticism and suppression of the pituitary adrenal axis after prolonged treatment. This effect is more likely to occur in infants and children and if occlusive dressings are used or large areas of skin treated. Napkins may act as occlusive dressings.

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

The active substance is a well-established topical corticosteroid, with an activity classified at potent.

5.2 Pharmacokinetic properties

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
Citric acid anhydrous
Propyl parahydroxybenzoate (E216)
Butyl parahydroxybenzoate
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

The shelf-life expiry date of this product shall be the date shown on the container and outer package of the product on the market in the country of origin

6.4 Special precautions for storage

Do not store above 25ºC.
Do not refrigerate or freeze.

6.5 Nature and contents of container

Aluminium tube with plastic cap containing 30 g.

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 Parallel Product Authorisation Holder

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 Parallel Product Authorisation Number

PPA 465/177/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 10th November 2006

10 DATE OF REVISION OF THE TEXT

October 2008