IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0030/015/001
Case No: 2045318

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

Novartis Consumer Health UK Ltd

Wimblehurst Road, **Horsham**, **West Sussex RH12 5AB**, **England**

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

Vioform Hydrocortisone 3/1 % 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 **12/05/2008**.

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

Vioform Hydrocortisone 3/1 % w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Clioquinol 3% w/w
Hydrocortisone 1% w/w
Also contains Cetostearyl alcohol

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cream
A white to faintly yellow, homogenous cream with a characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Exudative and secondarily infected eczema and dermatitis, including atopic eczema, primary irritant dermatitis, allergic and seborrhoeic dermatitis. Infected insect bite reactions. Genital or peri-anal intertrigo.

4.2 Posology and method of administration

Method of application: The preparation should be applied sparingly to the affected area, 1-3 times daily. Treatment should be limited to 7 days. Occlusive dressings should not be used.

If there is little improvement after 7 days treatment with Vioform Hydrocortisone Cream, the appropriate microbiological investigations should be carried out and local or systemic antibiotic treatment given.

Use in the elderly: There is no evidence to suggest that dosage should be different in the elderly.

Use in children: Vioform Hydrocortisone is contraindicated in children below the age of two years.

Method of administration: For cutaneous use

4.3 Contraindications

Use in patients hypersensitive to the active ingredients including iodine.

Primary bacterial, viral or fungal infections of the skin. Secondary infections due to yeasts.

Contact with mucosa or conjunctiva should be avoided.

Application to ulcerated areas.

Use in children below the age of 2 years.

4.4 Special warnings and precautions for use

Application to relatively large and/or eroded areas of skin, use of occlusive dressings and treatment for longer than one week, should be avoided, because this may lead to a marked increase in protein-bound iodine (PBI). Thyroid function tests such as PBI, radioactive iodine and butanol extractable iodine, may be affected, consequently it is advisable that such tests are not performed within one month of discontinuing treatment. However, other thyroid function tests, such as the T resin sponge test or T determination are unaffected.

Long-term continuous topical therapy should be avoided since this can lead to adrenal suppression even without occlusion.

There have been a few reports in the literature of the development of cataracts in patients who have been using corticosteroids for prolonged periods of time. Although it is not possible to rule out systemic corticosteroids as a known factor, prescribers should be aware of the possible role of corticosteroids in cataract development.

The ferric chloride test for phenylketonuria may yield a false-positive result when clioquinol is present in the urine.

Vioform Hydrocortisone should be used with caution in patients suffering from hepatic and/or renal failure.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

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 small risk of such effects in the human foetus.

It is not known whether the active substances of Vioform Hydrocortisone and/or their metabolites pass into the breast milk after topical administration. Use in lactating mothers should only be at the doctor’s discretion.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Vioform Hydrocortisone is usually well tolerated but occasionally at the site of application, there may be signs of irritation such as a burning sensation, itching or skin rash. Hypersensitivity reactions may also occasionally occur. Treatment should be discontinued if patients experience severe irritation or sensitisation.

Vioform Hydrocortisone may cause hair discoloration.

4.9 Overdose

Vioform Hydrocortisone Cream is for cutaneous (external) use only. If accidental ingestion of large quantities occurs, there is no specific antidote and general measures to eliminate the drug and reduce its absorption should be undertaken. Symptomatic treatment should be administered as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Vioform Hydrocortisone Cream combines the anti-fungal and anti-bacterial properties of clioquinol with the anti-inflammatory, anti-allergic and anti-pruritic effects of hydrocortisone.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Sodium lauryl sulphate
2-Phenoxyethanol
Cetostearyl alcohol
Cetyl palmitate
White soft paraffin
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

5 years

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and contents of container

Internally lacquered aluminium tube.

Pack size 30g.

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

Novartis Consumer Health UK Ltd
Wimblehurst Road
Horsham
West Sussex
RH12 5AB
England

8 MARKETING AUTHORISATION NUMBER

PA 30/15/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01st April 1977

Date of last renewal: 12th May 2008

10 DATE OF REVISION OF THE TEXT

January 2009