IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0002/018/001
Case No: 2055949

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

Bristol-Myers Squibb Pharmaceuticals Ltd

Swords, **Co. Dublin**, **Ireland**

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

Adcortyl in Orabase 0.1% w/w oromucosal paste

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 **16/12/2008**.

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

Adcortyl in Orabase 0.1% w/w oromucosal paste

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Triamcinolone Acetonide 0.1% w/w.

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Oromucosal paste.
Smooth, uniform, white to light tan oromucosal paste with characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Adcortyl in Orabase is indicated for aphthous ulcers, ulcerative stomatitis, denture stomatitis, desquamative gingivitis, erosive lichen planus and lesions of the oral mucosa of traumatic origin.

4.2 Posology and method of administration

Adults, Children and the Elderly: Application 2 to 4 times daily or as directed by the physician.

4.3 Contraindications

In patients with a history of hypersensitivity to the product components.

Use in the presence of untreated infections of bacterial, viral, tuberculous or fungal origin.

4.4 Special warnings and precautions for use

Continuous treatment for longer than three weeks should be avoided in patients under the age of three years because of the possibility of adrenocortical suppression or of growth suppression.

Prolonged use of uninterrupted occlusion or use with extensive occlusive dressings may suppress adrenocortical function.

Do not use on children under 12 years of age without medical supervision.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Pregnancy and lactation

This product should not be used in pregnancy or lactation unless considered essential by the physician. Studies in

animals showed teratogenic effects. There is as yet no evidence of a similar effect in human beings.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Triamcinolone acetonide in an oral paste is well tolerated. The possibility of the systemic effects which are associated with all steroid therapy should be considered.

4.9 Overdose

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see undesirable effects).

In the event of accidental ingestion, the patient should be observed and treated symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Triamcinolone acetonide is a potent fluorinated corticosteroid with rapid anti-inflammatory, antipruritic and anti-allergic actions.

When applied to large areas or when the skin is broken, or when administered under occlusive dressings, triamcinolone may be absorbed in sufficient amounts to cause systemic effects.

5.2 Pharmacokinetic properties

Triamcinolone has a plasma half-life of around five hours.

5.3 Preclinical safety data

See 4.6 "Pregnancy and lactation".

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gelatin
Liquid paraffin
Pectin
Polyethylene resin
Carmellose sodium

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

5 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Lined aluminium tubes, with polyethylene cap, containing 10g paste.

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

Bristol-Myers Squibb Pharmaceuticals Ltd
Swords
County Dublin

8 MARKETING AUTHORISATION NUMBER

PA 2/18/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1 April 1978

Date of last renewal: 1 April 2008

10 DATE OF REVISION OF THE TEXT

September 2008