IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0365/049/001
Case No: 2082431

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

UCB Pharma Limited

208 Bath Road, **Slough**, **Berkshire SL1 3WE**, **United Kingdom**

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

Corlan, 2.5 Milligram

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 **10/05/2010**.

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

Corlan 2.5mg Muco-Adhesive Buccal Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each muco-adhesive buccal tablet contains 2.5 mg Hydrocortisone as Hydrocortisone Sodium Succinate.

Excipients: Each tablet contains 67.742mg lactose

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Mucoadhesive Buccal tablet
White biconvex tablet engraved ‘Corlan Evans’ on one side.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the local management of aphthous ulceration of the mouth.

4.2 Posology and method of administration

Adults and children:

One pellet four times daily. Corlan pellets should not be sucked, but kept in the mouth and allowed to dissolve slowly in close proximity to the ulcers.

Maintenance therapy

When ulcers re-occur quickly, after withdrawal of treatment, maintenance therapy with reduced dosage is desirable for a period. Approximately 2-3 weeks.

4.3 Contraindications

Corlan Pellets should not be used in the presence of untreated oral infections of bacterial, viral, tuberculous or fungal origin. Hypersensitivity to any component of the product.

4.4 Special warnings and precautions for use

Withdrawal may result in acute rebound exacerbation of disease, acute adrenocortical insufficiency, polyarteritis.

Patients currently on corticosteroid therapy or those who have been on such treatment within the previous year may require special control measures if involved in anaesthesia, surgical procedures and other stress.

Withdrawal of corticosteroids should always be gradual and related to the duration of use.

If aphthous ulceration is severe or recurring, serious underlying disease should be excluded.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent administration of barbiturates, phenylbutazone, phenytoin may decrease corticosteroid levels, while, if anticoagulants are given with the corticosteroid, adjustment of dosage of the former is usually necessary.

The use of corticosteroids in the presence of other disorders or of drugs with specific actions (e.g. hypoglycaemics), impinging on the effects of corticosteroids will result in imbalance of control.

4.6 Pregnancy and lactation

Corticosteroids should only be used during pregnancy if considered essential by the physician. Systemic administration to animals can produce a teratogenic effect. Corticosteroids are excreted in breast milk.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Corticosteroid administration will result in certain effects, the severity, significance and extent of which vary with the dosage and duration of treatment and the particular corticosteroid used.

These include disturbance in electrolyte balance, mineral metabolism, glucose metabolism and gluconeogenesis, nitrogen depletion, diminished lymphoid tissue and immune response, inhibition of pituitary function, Cushingoid Syndrome, increase in blood coagulability, diminished inflammatory response and growth retardation in children.

Corticosteroids may worsen existing diabetes. Occasionally, topical steroid therapy may result in an exacerbation of local infection.

Hypersensitivity reactions have occurred with corticosteroids, mainly when administered topically.

Most topically applied corticosteroids may, under certain circumstances, be absorbed in sufficient amounts to produce systemic effects.

4.9 Overdose

Treatment is unlikely to be needed in cases of acute overdosage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: A01A C03.

None stated.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Acacia
Magnesium Stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

1 year.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Polypropylene child resistant container containing 20 buccal tablets in a carton.

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

UCB Pharma Limited
208 Bath Road
Slough
Berkshire SL1 3WE
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 365/49/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07 July 1993

Date of last renewal: 07 July 2008

10 DATE OF REVISION OF THE TEXT

February 2009