IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0102/015/001
Case No: 2039740

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

Norgine Limited

Chaplin House, **Widewater Place, Moorhall Road**, **Harefield**, **Uxbridge**, **Middlesex UB9 6NS**, **United Kingdom**

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

Pyralvex Oromucosal Solution

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 **21/08/2007** until **31/03/2008**.

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

Pyralvex Oromucosal Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Pyralvex contains the following active substances in each 1ml of solution:

Rhubarb extract	50 mg (equivalent to 5 mg anthraquinone glycosides)
Salicylic Acid	10mg

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Brown oromucosal solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief of pain associated with recurrent mouth ulcers and denture irritation.

4.2 Posology and method of administration

Adults (including the elderly): To be applied to the inflamed oral mucosa (after removing any dentures) three or four times daily using the brush provided. Avoid rinsing of the mouth or eating for 15 minutes after application. Any discolouration which may occur will disappear during normal cleaning of the teeth.
Children: Not recommended below the age of 12 years.

4.3 Contraindications

Hypersensitivity to any of the constituents.

4.4 Special warnings and precautions for use

Each bottle of PYRALVEX should be used by only one person.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Animal studies are insufficient with respect to effects on pregnancy and- or embryonal/foetal development. The potential risk for humans is unknown. Caution should be exercised when prescribing to pregnant women.
Anthranoid glycosides derived from rhubarb may be excreted in breast milk. However, at therapeutic doses of Pyralvex, it is not known whether these, or salicylic acid are excreted in breast milk. A decision on whether to continue

breast-feeding or to continue therapy with Pyralvex should be made taking into account the benefit of breast-feeding to the child and benefit of Pyralvex therapy to the women.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Gastrointestinal Disorders
A transient local burning sensation at the site of application occurs very commonly (>1/10).
Temporary discolouration of teeth or oral mucosa have been described commonly (>1/100, <1/10) following administration of Pyralvex (see also section 4.2)

4.9 Overdose

Overdose associated with local application is unlikely, although the extent of systemic absorption of salicylic acid and anthranoid derivatives is not known. Systemic overdose following ingestion might lead to abdominal cramping, diarrhoea and possibly salicylism (presenting as hyperventilation, tinnitus, deafness, vasodilation, sweating).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological studies have shown that the active ingredients of PYRALVEX display anti-inflammatory, analgesic and anti-microbial properties, which are the basis of its clinical efficacy.

5.2 Pharmacokinetic properties

Systemic availability of PYRALVEX is unlikely to be significant, owing to the low levels of ingredients administered.

5.3 Preclinical safety data

Preclinical studies indicate that at clinically effective doses, the ingredients in PYRALVEX are unlikely to have any potential for toxic effects.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol
Water

6.2 Incompatibilities

None known

6.3 Shelf Life

The shelf life is 5 years.

6.4 Special precautions for storage

Store below 25˚C.

6.5 Nature and contents of container

An amber glass bottle with brush applicator (PP screw cap with PE stem and nylon filament brush), containing 10 ml of solution.

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

Norgine Limited
Chaplin House
Widewater Place
Moorhall Road
Harefield
Uxbridge
Middlesex, UB9 6NS
Untied Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 102/15/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1983

Date of last renewal: 1st April 2003

10 DATE OF REVISION OF THE TEXT

August 2007