SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Pyralvex Solution, oromucosal solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Rhubarb extract 50 mg (equivalent to 5 mg anthraquinone glycosides)

Salicylic acid 10mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

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) and children 16 years and over: To be applied to the inflamed oral mucosa (after removing any dentures) three or four times daily using the brush provided.

Seek medical advice if no improvement in condition – maximum length of use is 7 days.

Children: Contraindicated below the age of 16 years.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

Not to be used in children and adolescents under the age of 16. This is because there is a possible association between salicylates and Reye's Syndrome when given to children. Reye's Syndrome is a very rare disease which affects the brain and liver and can be fatal.

4.4 Special warnings and precautions for use

Salicylate toxicity can result if the stated frequency of application is exceeded.

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

Anthraquinone glycoside/salicylic acid contains 59,5 vol.-% alcohol.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Pregnancy
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.

Breast-feeding
Anthranoid glycosides derived from rhubarb may be excreted in breast milk. However, at therapeutic doses of anthraquinone glycoside/salicylic acid, 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 anthraquinone glycoside/salicylic acid should be made taking into account the benefit of breast-feeding to the child and benefit of anthraquinone glycoside/salicylic acid therapy to the woman.

4.7 Effects on ability to drive and use machines

Anthraquinone glycoside/salicylic acid has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Within the system organ classes, adverse reactions are listed under headings of frequency (number of patients expected to experience the reaction), using the following categories:

Very common (≥1/10)

Common (≥1/100 to <1/10)

Uncommon (≥1/1,000 to <1/100)

Rare (≥1/10,000 to <1/1,000)

Very rare (≥1/10,000)

Not known (cannot be estimated from the available data)

Immune system disorders
Very rare: Allergic reactions

Gastrointestinal disorders
Common: Temporary discolouration of teeth or oral mucosa

Skin and subcutaneous tissue disorders
Frequency not known: Rash and urticaria

General disorders and administration site conditions
Very common: Transient local burning sensation at the site of application

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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).

Salicylate toxicity can result if stated frequency of application is exceeded. Do not exceed the stated frequency of application.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic properties

Systemic availability of anthraquinone glycoside/salicylic acid is unlikely to be significant, owing to the low levels of ingredients administered.

5.3 Preclinical safety data

There is some evidence of genotoxic risk with rhubarb extract and related anthranoids, the relevance of these findings to anthraquinone glycoside/salicylic acid is unknown.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol

Water

6.2 Incompatibilities

None known.

6.3 Shelf life

The shelf life is 3 years.

6.4 Special precautions for storage

Store below 25ºC.

6.5 Nature and contents of container

An amber glass bottle with brush applicator containing 10ml of solution.

6.6 Special precautions for disposal

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.

7 MARKETING AUTHORISATION HOLDER

Mylan Products Ltd.,

Station Close,

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EN6 1TL,

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 46302/0139

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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