Pyralvex®

SCHEDULING STATUS: SO

PROPRIETARY NAME (AND DOSAGE FORM):
PYRALVEX® Solution

COMPOSITION: Each 1 ml contains:

Rhubarb extract (equivalent to 0,003 g of anthraquinone glycosides)	0,05 g
Salicylic acid	0,01 g
Ethanol (96 %)	59,5 % v/v

Other Excipients: Purified water

PHARMACOLOGICAL CLASSIFICATION:
A 16.4 Ear, Nose and Throat Preparations – Naso-Pharyngeal and Bucco-Pharyngeal Antiseptics.

PHARMACOLOGICAL ACTION: PYRALVEX® has anti-inflammatory, antiseptic and analgesic action in inflamed conditions of the bucco-pharyngeal mucosa.

INDICATIONS: Acute and chronic inflammations of the buccal mucosa and gingiva.

CONTRAINDICATIONS: Hypersensitivity to the active substances or to any of the excipients of **PYRALVEX®**. Not to be used in children under the age of 12. This is because there is an association between systemic salicylates and Reye's Syndrome in children.

WARNINGS: Do not exceed the stated frequency of application. Salicylate toxicity can result if the stated frequency of application is exceeded. Discolouration of teeth, dentures and dental prostheses.

INTERACTIONS: None known.

DOSAGE AND DIRECTIONS FOR USE:
Adults and children 12 years and over: Apply to the inflamed area with brush provided (after removing dentures) 3-4 times per day. Do not rinse the mouth or eat or drink immediately after use.

Seek medical advice if there is no improvement in condition – maximum length of use is 14 days.

Children under 12 years: PYRALVEX® is contraindicated below the age of 12 years (see contraindications)

PREGNANCY AND LACTATION: Safety in pregnancy and lactation has not been established.
Animal studies are insufficient with respect to effects on pregnancy and- or embryonal/fetal development.
The potential risk for humans is unknown. Caution should be exercised when prescribing **PYRALVEX®** to pregnant women. Anthraquinone 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 woman.

SIDE EFFECTS AND SPECIAL PRECAUTIONS: The following frequencies are based on the following system organ class conversion.
Very common (≥1/10), Common (≥1/100 to <1/10), Uncommon (≥1/1000 to <1/100), Rare (≥1/10 000 to <1/1000), Very rare (<1/10 000), Not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse Reaction
Immune Disorders	Not known	Allergic reactions, including rash and urticaria.
Gastrointestinal Disorders	Very common	Transient local burning sensation

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT: None known.

IDENTIFICATION: A red-brown liquid with a characteristic taste and odour.

PRESENTATION: Packed in 10 ml amber, glass bottles. An applicator brush is included with each packaging.

STORAGE INSTRUCTIONS: Store in well-closed containers at or below 25°C.

KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBER: H1494 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT:
Mylan (Pty) Ltd.

4 Brewery Street, Isando, Johannesburg, South Africa, 1600

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
22 November 2012

Pyralvex®

SKEDULERINGSTATUS: SO

EIENDOMSNAAM (EN DOSEERVORM):
PYRALVEX® Oplossing

SAMESTELLING: Elke 1 ml bevat:

Rubarb ekstrak (gelykstaande aan 0,003 g antrakinonglikosiede)	0,05 g
Salisielsuur	0,01 g
Etanol (96 %)	59,5 % v/v

Ander Eksipiente: Gesuiwerde Water

FARMAKOLOGIESE KLASSIFIKASIE:
A 16.4 Oor-, Neus- and Keelpreparate – Naso-Faringeale en Bukka-Faringeale Antiseptikum.

FARMAKOLOGIESE WERKING: PYRALVEX® het 'n anti-inflammatoriese, antiseptiese en analgetiese werking in ontsteekte toestande van die bukka-faringeale slymvlies.

INDIKASIES: Akute en kroniese inflammasie van die bukkale slymvlies en gingiva.

KONTRA-INDIKASIES: Hipersensitiwiteit vir die aktiewe bestandele of enige van die eksipiënte van **PYRALVEX®**. Behoort nie by kinders onder die ouderdom van 12 jaar gebruik te word nie. Dit is omdat daar 'n assosiasie is tussen sistemiese salisilate en Reye-sindroom in kinders.

WAARSKUWINGS: Moenie die aangeduide frekwensie van aanwending oorskry nie. Indien die aangeduide frekwensie oorskry word, kan dit lei tot salisilaatvergiftiging. Verkleuring van tande, vals tande en tandprosteses.

INTERAKSIES: Geen bekend.

DOSIS EN GEBRUIKSAANWYSINGS:
Volwassenes en kinders 12 jaar en ouer: Wend 3-4 keer per dag aan die ontsteekte oppervlak met die borseltjie wat voorsien word (nadat vals tande verwyder is). Moenie die mond spoel of eet onmiddelik na gebruik nie.
Verkry mediese advies indien daar geen verbetering van die toestand is nie – die maksimum duur van gebruik is 14 dae.
Kinders onder 12 jaar: PYRALVEX® is teenaangedui by 'n ouderdom jonger as 12 jaar (sien kontra-indikasies).

SWANGERSKAP EN BORSVOEDING: Veiligheid tydens swangerskap en borsvoeding is nie bewys nie.
Studies op diere is onvoldoende m.b.t. die uitwerking op swangerskap en/of embrionale/fetale ontwikkeling.
Die potensiële risiko vir mense is onbekend. Versigtigheid moet aan die dag gelê word wanneer **PYRALVEX®** vir swanger vroue voorgeskryf word.
Antrakinoon glikosied verkry uit Rabarber mag in borsmelk uitgeskei word. Teen terapeutiese dosisse van **PYRALVEX®** is dit egter nie bekend of dit of salisiliensuur in borsmelk uitgeskei word nie. 'n Besluit of daar met borsvoeding voortgegaan moet word en of daar met behandeling met **PYRALVEX®** voortgegaan moet word, behoort gemaak te word deur die voordeel van borsvoeding vir die kind en die voordeel van behandeling met **PYRALVEX®** vir die vrou, in ag te neem.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Die volgende frekwensies is gebaseer op die volgende sistemiese orgaan klas omsetting.
Baie algemeen (≥ 1/10), Algemeen (≥1/100 tot <1/10), Seldsaam (≥1/1000 tot <1/100), Skaars (≥1/10 000 tot <1/1000), Baie skaars (<1/10 000), Nie bekend (kan nie vanuit die beskikbare data beraam word nie).

Sistemies Orgaan Klas	Frekwensie	Ongunstige Reaksie
Immuun aandoeninge	Nie bekend	Allergiese reaksies, insluitend uitslag en urtikarie
Gastro-intestinale aandoeninge	Baie algemeen	Verbygaande lokale brandsensasie

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Geen bekend.

IDENTIFIKASIE: 'n Rooi-bruin vloeistof met 'n kenmerkende smaak en geur.

AANBIEDING: Verpak in 10 ml amberkleurige glasbottels. 'n Borseltjie vir aanwending is ingesluit by elke verpakking.

BERGINGSAANWYSINGS: Bewaar in deeglik toegemaakte houers teen of benede 25°C.

HOU BUITE DIE BEREIK VAN KINDERS.

VERWYSINGSNOMMER: H1494 (Wet 101/1965)

NAAM EN BESIGHEIDSADRES VAN DIE AANSOEKER:
Mylan (EDMS) BPK
4 Brewery Straat, Isando, Johannesburg, Suid Afrika, 1600

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