



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

SKEDULERINGSSTATUS: **SO**

EIENDOMSNAAM (EN DOSEERVORM):

PYRALVEX[®] Oplissing

SAMESTELLING: Elke 1 ml bevat:

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

Ander Eksipiënte: 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 bukka 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 tandprotheses.

INTERAKSIES: Geen bekend.

DOSIS EN GEBRUIKSAANWYSINGS:

Volwasse 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 vrou voorgeskryf word.

Antrakinoon glikosied verkry uit Rabarber mag in borsmelk uitgeskei word. Teen terapeutiese dosisse van PYRALVEX[®] is dit egter nie bekend of dit 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 VOORSORGMATREËLS: 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
Immune aandoeninge	Nie bekend	Allergiese reaksies, insluitend uitslag en urtikarie
Gastro-intestinale aandoeninge	Baie algemeen	Verbygaande lokale brandsensasie

BEKEDE 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.

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

HOU BUIE DIE BEREIK VAN KINDERS.

VERWYSINGSNUMMER: H1494 (Wet 101/1965)

NAAM EN BESIGHEIDSADRES VAN DIE AANSOEKER: Mylan (EDMS) BPK

4 Brewery Straat, Isando, Johannesburg, Suid Afrika, 1600

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET: 22 November 2012

www.mylansa.co.za

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully because it contains important information for you

This medicine is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use **PYRALVEX**[®] carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.

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	

PYRALVEX[®] contains anthraquinone glycosides, which have anti-inflammatory actions. It also contains salicylic acid which helps to relieve pain.

APPROVED INDICATION AND USE, THAT IS, WHAT **PYRALVEX**[®] IS USED FOR

For relief of pain and inflammation of the gums and lining of the mouth.

INSTRUCTION BEFORE USING **PYRALVEX**[®]

Do not use **PYRALVEX**[®] if you are sensitive to Rhubarb extract or salicylic acid or any of the other ingredients of **PYRALVEX**[®]. If you are pregnant or breast feeding your baby while using **PYRALVEX**[®], please consult your doctor, pharmacist or other health care professional for advice.

Should not be used by children below the age of 12 years. Each bottle of **PYRALVEX**[®] should be used by only one person. Being a coloured liquid, **PYRALVEX**[®] can stain material and care should, therefore, be taken to ensure that the liquid is not spilt, or dropped on to clothing. **PYRALVEX**[®] can also discolour teeth, dentures and dental prostheses, temporarily.

INSTRUCTIONS ON HOW TO USE **PYRALVEX**[®]

Do not swallow.

Adults and children older than 12 years of age:

To be applied to the inflamed sore areas of the mouth, (after removing dentures) three or four times daily, using the brush provided. Always replace the cap after use.

Avoid rinsing the mouth or eating for 15 minutes after application. Any discolouration, which may occur, will disappear during normal cleaning of the teeth.

Seek medical advice if there is no improvement in condition – do not use for longer than 14 days.

POSSIBLE SIDE EFFECTS

The following side effects have been reported. Allergic reactions, including rash and urticaria (itchy skin). Transient local burning sensation at the site of application. Temporary discolouration of teeth or oral mucosa.

STORAGE AND DISPOSAL INFORMATION

Store at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN

Return all unused medicine to your pharmacist – do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

PRESENTATION

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

IDENTIFICATION

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

REGISTRATION NUMBER

H1494 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Mylan (Pty) Ltd.

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

DATE OF PUBLICATION OF THE PATIENT

INFORMATION LEAFLET: 22 November 2012

PASIËNTINLIGTINGSBLAADJIE

Lees alles op hierdie voubiljet sorgvuldig deur want dit bevat belangrike inligting

Hierdie medisyne is beskikbaar sonder 'n doktersvoorskrif vir die behandeling van 'n ligte ongesteldheid. U moet **PYRALVEX**[®] nietemin versigtig gebruik om die beste resultate te verkry.

- Bewaar hierdie voubiljet. U mag dit moontlik weer moet lees.
- Raadpleeg u apteker indien u meer inligting of advies benodig.

SKEDULERINGSSTATUS: **SO**

EIENDOMSNAAM EN DOSEERVORM

PYRALVEX[®] Oplossing

SAMESTELLING: Elke 1 ml bevat

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

Ander Eksipiente: Gesuiwerde Water

PYRALVEX[®] bevat antrakinnoon glikosiede wat 'n anti-inflammatories uitwerking het. Dit bevat ook salisielsuur wat help om pyn te verlig.

GOEDGEKEURDE INDIKASIE EN GEBRUIK D.W.S. WAAR VOOR **PYRALVEX**[®] GEBRUIK WORD

Vir die verligting van pyn en inflammasie van die tandvleise en voering van die mond.

INSTRUKSIES VOOR DIE GEBRUIK VAN **PYRALVEX**[®]

Moenie **PYRALVEX**[®] gebruik indien u gevoelig is vir Rabarberekstrak of salisielsuur of enige van die bestandele van **PYRALVEX**[®] nie.

Indien u swanger is of u baba borsvoed terwyl u **PYRALVEX**[®] gebruik, raadpleeg asb. u dokter, apteker of ander gesondheidsorgwerker vir advies. Behoort nie deur kinders onder die ouderdom van 12 jaar gebruik te word nie. Elke bottle **PYRALVEX**[®] behoort deur slegs een persoon gebruik te word. Aangesien **PYRALVEX**[®] 'n gekleurde vloeistof is, kan dit materiaal vlek en daarom behoort voorsorg getref te word om te verseker dat die vloeistof nie op klere stort of drup nie. **PYRALVEX**[®] kan ook tande, vals tande en tandprosteses tydelik verkleur.

INSTRUKSIES VIR DIE GEBRUIK VAN **PYRALVEX**[®]

Moenie sluk nie.

Volwasse en kinders ouer as 12 jaar:

Gebruik die borseltjie wat voorsien word en wend drie of vier keer per dag aan op die ontsteekte, seer gedeeltes van die mond (nadat vals tande verwyder is). Plaas die doppie altyd terug na gebruik.

Vermag eet of spoeling van die mond vir 15 minute na aanwending. Enige verkleuring wat mag voorkom, verdwyn met reiniging van die tande.

Kry mediese advies indien daar geen verbetering van die toestand is nie – moenie vir langer as 14 dae gebruik nie.

MOONTLIKE NEWE-EFFEKTE

Die volgende nuwe-effekte is aangeteken.

Allergiese reaksies insluitend 'n uitslag en urtikarie (jeukende vel). Verbygaande plaaslike brand sensasie by die aanwendingsplek. Tydelike verkleuring van die tande of orale slymvlies.

BEGINGS- EN OPRUIMINGSINLIGTING

Bewaar teen of benede 25 °C.

HOU BUITE BEREIK VAN KINDERS

Neem alle ongebruikte medisyne terug na u apteker – moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) wegmaak nie.

AANBIEDING

'n Amberkleurige glasbottel met 10 ml oplossing en 'n doppie met borseltjie vir aanwending.

IDENTIFIKASIE

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

REGISTRASIENOMMER

H1494 (Wet 101/1965)

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFKAAT VAN REGISTRASIE

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