SOUTH AFRICAN PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S1

PROPRIETARY NAME AND DOSAGE FORM

OROCHLOR SPRAY SOLUTION

COMPOSITION

Each 100 ml of OROCHLOR SPRAY SOLUTION contains 266,625 mg benzocaine,

1,071425 ml chlorhexidine gluconate solution 20 %

Excipients:

Alcohol 96 % *v/v,* carmoisine red (C.I. 14720), flavour peppermint verona, flavour vanilla LR, glycerol, lemon oil soluble, Nipasept, ponceau 4R red (C.I. 16255), purified water, sodium cyclamate, saccharin sodium

Preservative:

Nipasept 0,005 % *m/v*

Contains alcohol: Alcohol 28,8 % *v/v*

Contains sweetener: Sodium cyclamate 400,0 mg, saccharin sodium 60,0 mg

Sugar free

CATEGORY AND CLASS

A 16.3 Surface anaesthetics

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Chlorhexidine is a bactericidal cationic antiseptic. It acts by destroying the cell membrane and precipitating the cell cytoplasm. It has been shown that chlorhexidine binds on to the hydroxyapatite of tooth enamel, on to the pellicle of the tooth surface and on to salivary mucins. It slowly desorbs from these sites to exert a prolonged bactericidal effect for several hours.

Benzocaine has mild local anaesthetic properties.

INDICATIONS

OROCHLOR SPRAY SOLUTION is indicated for temporary relief of pain and discomfort in sore throats due to colds (and accompanying tickling cough). It is also recommended for minor mouth irritations. OROCHLOR SPRAY SOLUTION is an antibacterial spray solution which inhibits the formulation of dental plaque. It is indicated as an aid in the treatment and prevention of gingivitis, and in the maintenance of oral hygiene, particularly in situations where tooth brushing cannot be adequately employed (e.g. following periodontal and other oral surgery or in mentally or physically handicapped patients).

CONTRAINDICATIONS

OROCHLOR SPRAY SOLUTION is contraindicated in patients with a history of sensitivity to local anaesthetics, chlorhexidine gluconate or any of the active ingredients.

OROCHLOR SPRAY SOLUTION is contraindicated in patients with low plasma-cholinesterase concentrations or in those receiving anticholinesterases.

WARNINGS AND SPECIAL PRECAUTIONS

When used in the mouth or throat, OROCHLOR SPRAY SOLUTION may impair swallowing and increase the risk of aspiration and patients should be cautioned not to eat for at least 60 minutes after the anaesthetic.

It should be given cautiously to patients with epilepsy, impaired cardiac conduction, shock, and myasthenia gravis or with liver damage.

INTERACTIONS

Patients taking anticholinesterases.

HUMAN REPRODUCTION

Not known.

DOSAGE AND DIRECTIONS FOR USE

Adults: 4 to 8 sprays every 4 hours with a maximum of 32 sprays a day.

Children 6 to 12 years: 2 to 4 sprays every 4 hours with a maximum of 16 sprays a day.

SIDE EFFECTS

Local skin sensitivity reactions may occur.

Prolonged use may cause discolouration of the teeth.

Taste disturbances and a burning sensation of the tongue may occur initially.

The systemic toxicity of benzocaine mainly involves the central nervous system and the cardiovascular system. Excitation of the CNS may be manifested by restlessness, excitement,

nervousness, dizziness, tinnitus, blurred vision, nausea and vomiting, muscle twitching and tremors, and convulsions. Numbness of the tongue and perioral region may appear as an early sign of systemic toxicity. Excitation may occur and may be followed by depression with drowsiness, respiratory failure, and coma.

There may be simultaneous effects on the cardiovascular system with myocardial depression and peripheral vasodilatation resulting in hypotension and bradycardia, arrhythmias and cardiac arrest may occur.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

Excitation with subsequent depression of the central nervous system.

Methaemoglobinaemia has occurred after absorption of benzocaine.

Treatments

When systemic reactions occur, steps should be taken to maintain the circulation and respiration and to control convulsions. Treatment is symptomatic and supportive.

IDENTIFICATION

A clear orange-red liquid, with chlorhexidine gluconate and ethanol odour.

PRESENTATION

100 ml are packed into a round, amber glass bottle and sealed with a white, polypropylene cap with a low density polyethylene liner.

STORAGE CONDITIONS

Store at or below 25 °C.

Protect from light.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

28/16.3/0057

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

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Date of registration: 07 February 1994

Date of the most recent amendment to the professional information as approved by the Authority: 10 October 1997

ZA_OROCSSOL_9710_00

SUID AFRIKANSE PROFESSIONELE INLIGTING VIR MEDISYNE VIR MENSLIKE GEBRUIK

SKEDULERINGSTATUS

S1

EIENDOMSNAAM EN DOSEERVORM

OROCHLOR SPRAY SOLUTION (oplossing)

SAMESTELLING

Elke 100 ml OROCHLOR SPRAY SOLUTION bevat 266,625 mg bensokaïen, 1,071425 ml chloorheksidienglukonaat oplossing 20 %

Eksipiënte:

Alkohol 96 % *v/v,* karmoïsien rooi (C.I. 14720), “verona” peppermentgeur, LR vanillageur, gliserol, oplosbare suurlemoenolie, Nipasept, “ponceau” 4R rooi (C.I. 16255), gesuiwerde water, natriumsiklamaat, natriumsakkarien

Preserveermiddel:

Nipasept 0,005 % *m/v*

Bevat alkohol: Alkohol 28,8 % *v/v*

Bevat versoeter: Natriumsiklamaat 400,0 mg, natriumsakkarien 60,0 mg

Suikervry

KATEGORIE EN KLAS

A 16.3 Oppervlakverdowingsmiddels

FARMAKOLOGIESE WERKING

Farmakodinamiese eienskappe

Chloorheksidien is ’n bakterisidiese kationiese ontsmettingsmiddel. Dit werk deur vernietiging van die selmembraan en ontketening van die sel sitoplasma. Dit is bewys dat chloorheksidien bind aan die hidroksi-apatiet van die tandemalje, aan die pellikel van die tandoppervlak en aan die speekselmusien. Dit desorbeer stadig vanuit hierdie ligging om ’n verlengde bakterisidiese effek vir etlike ure uit te oefen.

Bensokaïen het ligte plaaslike verdowende eienskappe.

INDIKASIES

OROCHLOR SPRAY SOLUTION is aangedui vir tydelike verligting van pyn en ongemak by seerkele as gevolg van verkoue (en gepaardgaande kielierige hoes). Dit word ook aanbeveel vir geringe mondirritasies. OROCHLOR SPRAY SOLUTION is ’n antibakteriële sproei oplossing wat die vorming van dentale plaak inhibeer. Dit is aangedui as ’n hulpmiddel by die behandeling en voorkoming van gingivitis, en by die instandhouding van mondhigiëne, veral by situasies waar die tande nie voldoende geborsel kan word nie (bv. na periodontale en ander mondchirurgie of by geestelike of fisies gestremde pasiënte).

KONTRA-INDIKASIES

OROCHLOR SPRAY SOLUTION is teenaangedui by pasiënte met ’n geskiedenis van sensitiwiteit teenoor plaaslike verdowingsmiddels, chloorheksidienglukonaat of vir enige van die aktiewe bestanddele.

OROCHLOR SPRAY SOLUTION is teenaangedui by pasiënte met lae plasma-cholienesterase konsentrasies of by dié wat anticholienesterase middels ontvang.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS

Wanneer gebruik word in die mond of keel, kan OROCHLOR SPRAY SOLUTION sluk inkort en die risiko tot aspirasie verhoog, en moet pasiënte gewaarsku word om vir ten minste 60 minute na die verdowingsmiddel nie te eet nie.

Dit moet met versigtigheid vir pasiënte met epilepsie, ingekorte kardiale geleiding, skok, en myasthenia gravis of met lewerskade gegee word.

INTERAKSIES

Pasiënte wat anticholienesterase middels neem.

MENSLIKE VOORTPLANTING

Onbekend.

DOSIS EN GEBRUIKSAANWYSINGS

Volwassenes: 4 tot 8 spreie elke 4 ure met ’n maksimum van 32 spreie per dag.

Kinders 6 tot 12 jaar oud: 2 tot 4 spreie elke 4 ure met ’n maksimum van 16 spreie per dag.

NEWE-EFFEKTE

Plaaslike vel sensitiwiteitsreaksies kan voorkom.

Verlengde gebruik kan verkleuring van die tande veroorsaak.

Smaakversteurings en ’n brandende sensasie op die tong kan aanvanklik voorkom.

Die sistemiese toksisiteit van bensokaïen behels hoofsaaklik die sentrale senuweestelsel en die kardiovaskulêre stelsel. Opwinding van die SSS kan deur rusteloosheid, opwinding,

senuweeagtigheid, duiseligheid, tinnitus, dowwe visie, naarheid en braking, spiertrekkings, en konvulsies geopenbaar word. Gevoelloosheid van die tong en peri-orale gedeelte kan as ’n vroeë teken van sistemiese toksisiteit verskyn. Opwinding kan voorkom en kan gevolg word deur depressie met lomerigheid, respiratoriese versaking, en koma.

Daar kan gelyktydige effekte op die kardiovaskulêre stelsel wees met miokardiale onderdrukking en perifere vasodilatasie wat lei tot hipotensie en bradikardie, aritmieë en hartstilstand kan voorkom.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELINGS DAARVAN

Simptome

Opwinding met gevolglike onderdrukking van die sentrale senuweestelsel.

Methemoglobinemie het al voorgekom na absorpsie van bensokaïen.

Behandeling

Wanneer sistemiese reaksies voorkom moet stappe geneem word om die sirkulasie en respirasie in stand te hou en om die konvulsies te beheer. Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE

’n Deursigtige, oranje-rooi vloeistof, met ’n chloorheksidienglukonaat en etanol reuk.

AANBIEDING

100 ml word verpak in ’n ronde, amberkleurige glasbottel en verseël met ’n wit, polipropileen doppie met ’n laedigtheidspoliëtileen voering.

BERGINGSAANWYSINGS

Bêre teen of benede 25 °C.

Beskerm teen lig.

Hou in die oorspronklike verpakking totdat dit benodig word vir gebruik.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER

28/16.3/0057

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE

PHARMACARE LIMITED

Healthcare Park

Woodlandsrylaan

Woodmead 2191

DATUM VAN PUBLIKASIE VAN DIE PROFESSIONELE INLIGTING VIR MEDISYNE VIR MENSLIKE GEBRUIK

Datum van registrasie: 07 Februarie 1994

Datum van mees onlangse wysiging tot die professionele inligting soos goedgekeur deur die Gesag: 10 Oktober 1997

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