SCHEDULING STATUS: Schedule 1
PROPRIETARY NAME AND DOSAGE FORM:

PRODOL SOLUTION

COMPOSITION: Active ingredients:
Each 1 ml contains:

Benzocaine	10 mg
Cetylpyridinium chloride	1 mg

Inactive ingredients:

Ethanol	15 % *v/v*
Glycerol	
Sugar free.	

PHARMACOLOGICAL CLASSIFICATION: A.4 Local anaesthetics
PHARMACOLOGICAL ACTION: PRODOL has local anaesthetic, fungicidal and bactericidal properties.
INDICATIONS: Alleviation of pain and discomfort caused by minor irritation from sore gums, fever blisters and denture irritation.
CONTRA INDICATIONS:
- Hypersensitivity to benzocaine, cetylpyridinium chloride or to any of the inactive ingredients or related substances of **PRODOL** (see **COMPOSITION**).
- **PRODOL** should not be used by people with a high temperature or serious sore throat, unless prescribed by a doctor.
- Do not use in infants younger than six (6) months.
- Patients receiving anticholinesterases (see **INTERACTIONS**) or those with low plasma cholinesterase concentrations.
- Patients with complete heart block.

WARNINGS AND SPECIAL PRECAUTIONS: When used in the mouth, local anaesthetics may impair swallowing and increase the risk of aspiration. Patients suffering from traumatic mucosa and sepsis should use **PRODOL** with care. If pain, redness, rash, irritation and swelling persist, or if infection occurs, discontinue use and consult a doctor or dentist. Do not use for longer than seven days.

Benzocaine, as in **PRODOL** should be given with caution to patients with epilepsy, impaired cardiac conduction or respiratory function, shock or hepatic impairment.
Patients with myasthenia gravis are particularly susceptible to the effects of local anaesthetics, such as **PRODOL**.

Effects on ability to drive and use machines:
PRODOL is not likely to affect the ability to drive a vehicle or operate machinery. However, caution is advised before performing tasks requiring attention, until the effects of **PRODOL** are known.

INTERACTIONS:
- Benzocaine may antagonise the action of sulphonamides or aminosalicylic acid.
- Benzocaine is contraindicated in patients receiving anticholinesterases (see **CONTRAINDICATIONS**).

PREGNANCY AND LACTATION: Safety and/or efficacy during pregnancy and lactation has not been established.
DOSAGE AND DIRECTIONS FOR USE: Children and adults:
Apply **PRODOL** solution to the affected area with a clean finger or a piece of cotton wool, every 3 to 4 hours.
Minimum quantities must be applied.
Do not exceed a maximum of five (5) drops per application.
Do not use for longer than seven (7) days.
SIDE EFFECTS: Systemic side effects may occur as a result of absorption of large amounts of **PRODOL** through mucous membranes or damaged skin. Systemic toxicity of local anaesthetics mainly involves the central nervous system and the cardiovascular system.

Blood and the lymphatic system disorders:
Less frequent: Methaemoglobinaemia (infants younger than 3 months appear to be susceptible to induced methaemoglobinaemia due to their limited enzyme capacity).
Immune system disorders:
Less frequent: Allergic reactions may occur as a result of sensitisation by prolonged or repeat topical use or handling, and may present as types I (e.g. anaphylaxis) and type IV (i.e. delayed reaction) reactions.
Psychiatric disorders:
Less frequent: Excitement, excitation (may be transient), depression (with drowsiness).
Nervous system disorders:
Less frequent: Restlessness, paraesthesia, nervousness, dizziness, tremors, convulsions, numbness of the tongue and perioral region, lightheadedness.
Eye disorders:
Less frequent: Blurred vision.
Ear and labyrinth disorders:
Less frequent: Tinnitus.
Cardiac disorders:
Less frequent: Myocardial depression, bradycardia, arrhythmia, cardiac arrest.
Vascular disorders:
Less frequent: Peripheral vasodilatation, hypotension.
Respiratory, thoracic and mediastinal disorders:
Less frequent: Respiratory failure, coma.
Gastrointestinal disorders:
Less frequent: Nausea and vomiting.
Musculoskeletal, connective tissue and bone disorders:
Less frequent: Muscle twitching.
KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT: See **SIDE EFFECTS**.
Benzocaine has low systemic toxicity. Excess ingestion of the solution may result in nausea and vomiting. Should symptoms of dyspnoea or cyanosis appear, discontinue treatment immediately and consult a doctor.
Treatment is symptomatic and supportive.
IDENTIFICATION: A clear, off-white, transparent viscous liquid, slightly sweet and odourless.
PRESENTATION: 20 ml round amber glass bottles with a dropper and cap.
STORAGE INSTRUCTIONS:
Store well-closed at or below room temperature (25 °C). Protect from light.
KEEP OUT OF REACH OF CHILDREN.
REGISTRATION NUMBER: Z/4/111
NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Brunel Laboratoria (Pty) Ltd
1 Van Tonder Street
Sunderland Ridge
Centurion
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DATE OF PUBLICATION OF THE PACKAGE INSERT:
Date on the registration certificate: 12/03/1996

SKEDULERINGSTATUS: Skedule 1
EIENDOMSNAAM EN FARMASEUTIESE VORM:

PRODOL OPLOSSING

SAMESTELLING: Aktiewe bestanddele:
Elke 1 ml bevat:

Bensokaïen	10 mg
Setielpiridiniumchloried	1 mg

Onaktiewe bestanddele:

Etanol	15 % *v/v*
Gliserol	
Suiker vry.	

FARMAKOLOGIESE KLASSIFIKASIE: A.4 Lokale verdowing.
FARMAKOLOGIESE WERKING: PRODOL het lokaal verdowende, swamdodende en bakteriedodende eienskappe.
INDIKASIES: Vir die verligting van pyn en ongemak veroorsaak deur geringe irritasie van seer tandvleis, koorsblare en die irritasie van kunsgebit.
KONTRA-INDIKASIES:
- Hipersensitiwiteit vir bensokaïen, setielpiridiniumchloried of enige van die onaktiewe bestanddele of verwante stowwe van **PRODOL** (sien **SAMESTELLING**).
- **PRODOL** moet nie deur mense met 'n hoë temperatuur of ernstige seer keel gebruik word nie, tensy deur 'n dokter voorgeskryf.
- Moet nie vir babas jonger as ses (6) maande gebruik nie.
- Pasiënte wat anticholienesterase ontvang (sien **INTERAKSIES**) of diegene met lae plasma cholienesterase konsentrasies.
- Pasiënte met volledige hartblok.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS: Wanneer dit in die mond gebruik word, kan plaaslike verdowingsmiddels die vermoë om te sluk verswak en die risiko van aspirasie verhoog. Pasiënte wat aan beseerde mukosa en sepsis ly, moet **PRODOL** versigtig gebruik.
As pyn, rooiheid, uitslag, irritasie en swelling voortduur, of indien infeksie voorkom, staak gebruik en raadpleeg 'n dokter of tandarts. Moet nie langer as sewe dae gebruik nie.

Bensokaïen, soos in **PRODOL**, moet met omsigtigheid gegee word aan pasiënte met epilepsie, verswakte hartgeleiding of respiratoriese funksie, skok- of verswakte lewerfunksie. Pasiënte met myasthenia gravis is veral vatbaar vir die effekte van lokale verdowingsmiddels, soos **PRODOL**.

Effek op die vermoë om 'n voertuig te bestuur en masjinerie te hanteer.
PRODOL sal waarskynlik nie die vermoë om 'n voertuig te bestuur of masjinerie te hanteer beïnvloed nie. Versigtigheid met take wat die aandag vereis is nodig totdat die reaksie op **PRODOL** bekend is.

INTERAKSIES:
- Bensokaïen kan die werking van sulfoonamiede of aminosalisielsuur teenwerk.
- Bensokaïen is gekontra-indikeer by pasiënte wat anticholienesterase ontvang (sien **KONTRA-INDIKASIES**).

SWANGERSKAP EN LAKTASIE: Die veiligheid en effektiwiteit tydens swangerskap en laktasie is nie vasgestel nie.
DOSIS EN GEBRUIKSAANWYSINGS:
Kinders en volwassenes: Wend **PRODOL** oplossing aan op die aangetaste area met 'n skoon vinger of 'n stukkie watte, elke 3 tot 4 uur. Minimum hoeveelhede moet aangewend word.
Moenie meer as vyf (5) druppels op 'n keer gebruik nie.
Moenie langer as sewe (7) dae gebruik nie.
NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS: Sistemiese newe-effekte kan voorkom as gevolg van die absorpsie van groot hoeveelhede **PRODOL** deur slymvliese of beskadigde vel.
Sistemiese toksisiteit van plaaslike verdowingsmiddels behels hoofsaaklik die sentrale senuweestelsel en die kardiovaskulêre stelsel.

Bloed en limfstelsel versteurings:
Minder algemeen: Methemoglobienemie (babas jonger as 3 maande blyk vatbaar vir geïnduksieerde methemoglobienemie te wees as gevolg van hul beperkte ensiemkapasiteit).
Immuunstelsel versteurings:
Minder algemeen: Allergiese reaksies kan voorkom as gevolg van sensitisering deur langdurige of herhaalde gebruik of hantering, en kan voorkom as tipe I (bv. anafilakse) en tipe IV (dws vertraagde reaksie) reaksies.
Psigiatriese versteurings:
Minder algemeen: Opgewondenheid (kan verbygaande wees), depressie (met slaperigheid).
Senuweestelsel versteurings:
Minder algemeen: Rusteloosheid, parestesie, senuweeagtigheid, duiseligheid, bewerigheid, stuiptrekkings, gevoelloosheid van die tong- en periorale gebied, lighoofdigheid.
Versteurings van die oë:
Minder algemeen: Versteurde visie.
Oor en labirint versteurings:
Minder algemeen: Tinnitus.
Kardiovaskulêre versteurings:
Minder algemeen: Miokardiale depressie, bradikardie, aritmieë, hartstilstand.
Versteuring van die bloedvatstelsel:
Minder algemeen: Perifere vasodilatasie, hipotensie.
Respiratoriese, torakale en mediastinale versteurings:
Minder algemeen: Respiratoriese versaking, koma.
Gastroïntestinale versteurings:
Minder algemeen: Naarheid, braking.
Versteurings van die Muskuloskeletale stelsel, bindweefsel en been:
Minder algemeen: Spiertrekkings.
BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN: Sien **NEWE-EFFEKTE.**
Bensokaïen het 'n lae sistemiese toksisiteit. Oormatige inname van die oplossing mag lei tot naarheid en braking. Indien simptome van dispnee of sianose voorkom, moet die behandeling onmiddellik gestaak word en 'n dokter geraadpleeg word.
IDENTIFIKASIE: 'n Helder afwit deurskynende viskeuse oplossing, effens soet en reukloos.
AANBIEDING: 20 ml ronde amber glas bottel met 'n drupper en 'n skroefdop.
BERGINGSAANWYSINGS: Bewaar by of benede kamertemperatuur (25 °C). Hou die bottel dig toegedraai. Beskerm teen lig.
HOU BUITE DIE BEREIK VAN KINDERS.
REGISTRASIENOMMER: Z/4/111
NAAM EN BESIGHEIDSADRES VAN DIE REGISTRASIEHOUER:
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DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:
Datum van registrasie: 12/03/1996