Patient Information Leaflet for PRODOL
SCHEDULING STATUS: Schedule 1
PROPRIETARY NAME AND DOSAGE FORM:

PRODOL SOLUTION

Read all of this leaflet carefully before you start using PRODOL:
Keep this leaflet. You may need to read it again.
If you have further questions, please ask your doctor or pharmacist.
WHAT PRODOL CONTAINS:
Active ingredients:
Each 1 ml contains:

Benzocaine	10 mg
Cetylpyridinium chloride	1 mg

Inactive ingredients:

Ethanol	15 % *v/v*

Glycerol
Sugar free.
WHAT PRODOL IS USED FOR:
PRODOL will ease the pain and discomfort caused by minor irritation from sore gums, fever blisters and dentures (false teeth).

BEFORE YOU USE PRODOL:
Do not use PRODOL:
- If you are allergic to benzocaine, cetylpyridinium chloride or to any of the ingredients of **PRODOL** (see **WHAT PRODOL CONTAINS**).
- If you have a high temperature or bad sore throat you should not use **PRODOL**, unless told to by a doctor.
- In babies younger than six (6) months.
- If you have serious heart problems, such as a heart block.

Take special care with PRODOL:
- If you have any mouth sores or an infection in your mouth. If pain, redness, rash, irritation and swelling persist, or if infection occurs, discontinue use and consult your doctor or dentist. Do not use for longer than seven days.
- If you have epilepsy, heart, respiratory or liver problems.
- If you have myasthenia gravis (characterised by muscle weakness) consult your doctor before using **PRODOL**.

Taking PRODOL with food and drink:
Do not eat or drink directly after applying **PRODOL**, as it can make your mouth and throat numb, and affect swallowing.

Pregnancy and breastfeeding:
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using **PRODOL**.
Driving and using machinery:
PRODOL is not likely to affect your ability to drive a vehicle or operate machinery. However, take special care before performing tasks requiring your attention, until you know how **PRODOL** will affect you.
Using other medicines with PRODOL:
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicine.)
The following medicines may cause an interaction with **PRODOL**:
- Sulphonamides (used to treat acne or urinary tract infections).
- Aminosalicylic acid (used to treat tuberculosis (TB)).
- Anticholinesterases (used to relieve muscular weakness in myasthenia gravis or treat glaucoma).

HOW TO USE PRODOL:
Rub a few drops of **PRODOL** solution onto the painful part of the mouth or gums, every 3 to 4 hours, using a clean finger or a piece of cotton wool.
Do not use more than five (5) drops at a time.
Do not use for longer than seven (7) days.
Do not share medicines prescribed for you with any other person.
If you use more PRODOL than you should:
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
Swallowing large quantities of this medicine may cause nausea and vomiting.
If the skin becomes bluish, due to lack of oxygen (cyanosis), or if shortness of breath develops, stop treatment immediately and consult your doctor.
If you forget to take PRODOL:
Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS:
PRODOL can have side effects.
Not all side effects reported for **PRODOL** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using **PRODOL**, please consult your doctor, pharmacist or other healthcare professional for advice.
If any of the following happens, stop using **PRODOL** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **PRODOL**. You may need urgent medical attention or hospitalisation.
Allergic reactions may occur if **PRODOL** is handled often, or with frequent topical use.
Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
Less frequent:
- Convulsions (fits/seizures).
- Heart attack, slow irregular heartbeat, abnormal heartbeat, heart arrest (when your heart suddenly stops beating).
- Coma.

These are all very serious side effects. You may need urgent medical attention.
Tell your doctor if you notice any of the following:
Less frequent:
- Abnormally excited, feeling depressed (with sleepiness).
- Restlessness, "pins and needles", feeling nervous, dizziness, shaking, numbness of your tongue and mouth area.
- Blurred vision, ringing or buzzing in the ears.
- Low blood pressure (characterised by dizziness or light-headedness).
- Nausea and vomiting.
- Muscle contraction and relaxation which may be visible under the skin.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF PRODOL:
Store well-closed at or below room temperature (25 °C). Protect from light.
KEEP OUT OF REACH OF CHILDREN.
PRESENTATION OF PRODOL: 20 ml round amber glass bottles with a dropper and a cap.
IDENTIFICATION OF PRODOL: A clear, off-white, transparent viscous liquid, slightly sweet and odourless.
REGISTRATION NUMBER: Z/4/111
NAME AND ADDRESS OF REGISTRATION HOLDER:
Brunel Laboratoria (Pty) Ltd
1 Van Tonder Street
Sunderland Ridge
Centurion
0157
info@brunel.co.za
DATE OF PUBLICATION:
Date of registration: 12/03/1996

Pasiënte Inligtingsblad vir PRODOL
SKEDULERINGSTATUS: Skedule 1
EIENDOMSNAAM EN FARMASEUTIESE VORM:

PRODOL OPLOSSING

Lees hierdie inligtingsblad sorgvuldig deur voordat jy PRODOL begin gebruik:
Hou hierdie blad. Jy mag dalk dit weer moet lees. As jy verdere vrae het, vra jou dokter of apteker.
WAT PRODOL BEVAT:
Aktiewe bestanddele:
Elke 1 ml bevat:

Bensokaïen	10 mg
Setielpiridiniumchloried	1 mg

Onaktiewe bestanddele:

Etanol	15 % *v/v*

Gliserol
Suiker vry.
WAARVOOR PRODOL GEBRUIK WORD:
PRODOL sal die pyn en ongemak verlig wat veroorsaak word deur geringe irritasie van seer tandvleis, koorsblare en kunsgebit (vals tande).

VOORDAT JY PRODOL GEBRUIK:
Moenie PRODOL gebruik nie:
- As jy allergies is vir bensokaïen, setielpiridiniumchloried of enige van die bestanddele van **PRODOL** (sien **WAT PRODOL BEVAT**).
- Indien jy 'n hoë temperatuur of slegte seer keel het, tensy dit deur 'n dokter voorgeskryf is.
- Babas jonger as ses (6) maande.
- As jy ernstige hartprobleme het, soos 'n hartblok.

Neem spesiale sorg met PRODOL:
- As jy mondsere of 'n infeksie in jou mond het. As pyn, rooiheid, uitslag, irritasie en swelling voortduur, of indien infeksie ontwikkel, stop gebruik en raadpleeg jou dokter of tandarts. Moet nie langer as sewe dae gebruik nie.
- As jy epilepsie, hart-, respiratoriese- of lewerprobleme het.
- As jy myasthenia gravis het (gekenmerk deur spierswakheid), raadpleeg jou dokter voordat jy **PRODOL** gebruik.

Neem PRODOL met voedsel en vloeistof:
Moenie eet direk nadat **PRODOL** aangewend is nie, aangesien dit jou mond en keel kan verdoof en sluk kan beïnvloed.

Swangerskap en borsvoeding:
As jy swanger is of jou baba borsvoed, raadpleeg jou dokter, apteker of ander gesondheidswerker voordat jy **PRODOL** gebruik.
Bestuur en gebruik van masjinerie:
PRODOL sal waarskynlik nie jou vermoë om 'n voertuig te bestuur of masjinerie te gebruik beïnvloed nie. Voordat jy weet hoe **PRODOL** jou beïnvloed, moet jy eerder versigtig wees met take wat jou aandag vereis.
Gebruik van ander medisynes saam met PRODOL:
Vertel altyd jou gesondheidswerker as jy enige ander medisyne gebruik. (Dit sluit in aanvullende of tradisionele medisyne.)
Die volgende medisyne kan 'n interaksie met **PRODOL** veroorsaak:
- Sulfoonamiede (wat gebruik word om aknee of urienweginfeksies te behandel).
- Aminosalisielsuur (gebruik om tuberkulose (TB) te behandel).
- Anticholiensterase (gebruik om spierswakheid in myasthenia gravis te verlig of gloukoom te behandel).

HOE OM PRODOL TE GEBRUIK:
Vryf 'n paar druppels **PRODOL** oplossing elke 3 tot 4 ure, met 'n skoon vinger of 'n stukkie watte, op die pynlike gedeelte van die mond of tandvleis.
Moenie meer as vyf (5) druppels op 'n keer gebruik nie.
Moenie vir langer as sewe (7) dae gebruik nie.
Moenie medisyne wat vir jou voorgeskryf is, met enige ander persoon deel nie.
Indien jy meer PRODOL gebruik as wat jy moet:
In geval van oordosering, raadpleeg jou dokter of apteker. Indien hulle nie beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
Die inname van groot hoeveelhede van hierdie medisyne kan naarheid en braking veroorsaak.
As jou vel blou raak, weens 'n gebrek aan suurstof (sianose), of as jy kortasem raak, stop die behandeling dadelik en raadpleeg jou dokter.
Indien jy vergeet om PRODOL te neem:
Moenie 'n dubbeldosis neem as jy vergeet het om 'n dosis te neem nie.

MOONTLIKE NEWE EFFEKTE:
PRODOL kan newe effekte veroorsaak.
Nie alle newe effekte wat vir **PRODOL** aangemeld is, is in hierdie inligtingblad ingesluit nie. Indien jou algemene gesondheid verswak of indien jy enige ongemak ondervind terwyl **PRODOL** gebruik word, raadpleeg jou dokter, apteker of ander gesondheidswerkers vir advies.

As enige van die volgende gebeur, stop die gebruik van **PRODOL** en raadpleeg jou dokter dadelik of gaan na die ongevalle afdeling by jou naaste hospitaal:
- Swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat probleme veroorsaak om te sluk of asem te haal.
- Uitslag of jeuk
- Floute

Hierdie is almal baie ernstige newe effekte. As jy dit het, het jy moontlik 'n ernstige allergiese reaksie op **PRODOL**. Jy benodig dringende mediese aandag of hospitalisasie. Allergiese reaksies kan voorkom indien **PRODOL** gereeld hanteer word, of met gereelde aanwendings.
Vertel jou dokter dadelik of gaan na die ongevalle afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:
Minder algemeen:
- Konvulsies
- Hartaanval, stadige onreëlmatige hartklop, abnormale hartklop, hartarres (wanneer jou hart skielik ophou klop).
- Koma

Hierdie is almal ernstige newe effekte. Jy benodig dringende mediese aandag.
Raadpleeg jou dokter as jy enige van die volgende opmerk:
Minder algemeen:
- Abnormaal opgewonde, voel depressief (met slaperigheid).
- Rusteloosheid, "naalde en spelde", voel senuweeagtig, duiseligheid, bewe, gevoelloosheid van jou tong en mond.
- Onduidelike visie, gesuis in ore (tinnitus).
- Lae bloeddruk (wat gekenmerk word deur duiseligheid of lighoofdigheid).
- Naarheid en braking.
- Spier beweging (kontraksie en ontspanning) wat onder die vel sigbaar kan wees.

Lig asseblief jou dokter of apteker in as jy enige newe effekte ervaar wat nie in hierdie inligtingblad genoem word nie.

BEWARING EN WEGGOOI VAN PRODOL:
Bewaar by of benede kamertemperatuur (25 °C). Hou die bottel dig toegedraai. Beskerm teen lig.
HOU BUITE BEREIK VAN KINDERS.
AANBIEDING VAN PRODOL: 20 ml ronde amber glas bottel met 'n drupper en 'n skroefdop.
IDENTIFIKASIE VAN PRODOL: 'n Helder, afwit, deurskynende viskeuse oplossing, effens soet en reukloos.
REGISTRASIENOMMER: Z/4/111
NAAM EN ADRES VAN REGISTRASIEHOUER:
Brunel Laboratoria (Edms) Bpk
Van Tonderstraat 1
Sunderland Ridge
Centurion
0157
info@brunel.co.za
DATUM VAN PUBLIKASIE
Datum van registrasie: 12/03/1996

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
0157
info@brunel.co.za
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:
Brunel Laboratoria (Edms) Bpk
Van Tonderstraat 1
Sunderland Ridge
Centurion
0157
info@brunel.co.za
DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:
Datum van registrasie: 12/03/1996