SCHEDULING STATUS: S0

PROPRIETARY NAME (AND DOSAGE FORM): **TEEJEL® GEL (GEL)**

COMPOSITION:
Each 1 g contains:

Choline salicylate	87,1 mg
Alcohol	36,05 % m/m
Preservative:	
Cetalkonium chloride	0,1 mg

Sodium metabisulphate as antioxidant
Sugar free

PHARMACOLOGICAL CLASSIFICATION:
A 34. Local analgesics

PHARMACOLOGICAL ACTION:
Since the mouth is well endowed with pain nerve endings, lesions of the oral mucosa are apt to cause a pain level out of all proportion to their size. Even a small ulcer, which elsewhere would be considered trivial, causes the sufferer great discomfort, particularly if under pressure from a denture. The disturbance caused by a baby's teething is also well known. The prime need in treatment is for effective and rapid relief of pain by topical rather than systemic treatment. **TEEJEL GEL** supplies the answer to this need, and introduces a new approach to the treatment of pain and discomfort of the mouth, whatever its cause. Of the active ingredients, choline salicylate is a highly soluble and non-irritant salt of salicylic acid with powerful analgesic and anti-inflammatory properties. Unlike aspirin, it can be applied directly to mucous membranes without causing irritation. Cetalkonium chloride is a wide-spectrum bacterial agent which also has surface active properties. It is an effective inhibitor of Gram-positive and Gram-negative bacterial growth. Since it lowers surface tension, it facilitates contact of the choline salicylate with the affected area. Thus, employed together, these ingredients give quick and effective relief of pain and discomfort and promote rapid healing. Numerous clinical trials have confirmed this.

INDICATIONS:
Aphthous ulcers and other oral ulcerations and abrasions, denture sores, gingivitis, glossitis, thrush, herpes labialis, cheilosis, lesions of nasal mucosa (including the nasal and oral lesions of erythema multiforme and lichen planus), and infant teething.

CONTRAINDICATIONS:
Salicylate sensitivity.

DOSAGE AND DIRECTIONS FOR USE:
Using a well-washed finger or finger-stall, apply an adequate amount of the gel (usually about one centimetre expressed from the tube for adults and older children and half a centimetre for infants up to 2 years) to the tender area of buccal or nasal mucosa. Massage in well and repeat the application three or four times daily before meals and also at bedtime.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:
None observed. The slight tingling experienced is a direct effect of the alcohol content of the gel.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
As for aspirin. Gastric lavage with symptomatic and supportive treatment.

IDENTIFICATION:
TEEJEL GEL is a colourless gel flavoured with aniseed and menthol. The name **TEEJEL GEL** is printed on the tube.

PRESENTATION:
5 g tubes.

STORAGE INSTRUCTIONS:
Store in a cool place below 25 °C. KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBER:
G2805 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT:
Adcock Ingram Limited
1 New Road
Erand Gardens
Midrand, 1685
Private Bag X69
Bryanston, 2021
www.adcock.com

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
02 October 1979

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Mundipharma A.G., Switzerland

19419
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099

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PRINTERS PROOF

File Number	**ADC P 6167**
Repro Ticket	61700
Customer	**ADCOCK INGRAM**
Product	TEEJEL GEL PACKAGE INSERT
Code	19419 • 05/2011
Flat Size	**L** 176 **W** 120 (mm)
Folded Size	**L** 22 **W** 120 (mm)
Pharma Code	099
Colours	**• BLACK**
Proof No	**2**
Date	04/05/2011
Operator	CW
Proof Reader	

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Approved by	
Signature	
Date	

SKEDULERINGSTATUS: S0

EIENDOMSNAAM (EN DOSEERVORM): **TEEJEL® GEL (JEL)**

099

SAMESTELLING:
Elke 1 g bevat:
Choliensalisilaat 87,1 mg
Alkohol 36,05 % m/m
Preserveermiddel:
Setalkoniumchloried 0,1 mg
Natriummetabisulfiet as antioksidant
Suikervry

FARMAKOLOGIESE KLASSIFIKASIE:
A 34. Plaaslike analgetika

FARMAKOLOGIESE WERKING:
Omdat die mond goed bedeel is met senuwee-eindes, veroorsaak letsels aan die mondslymvliese 'n pyn wat buite alle verhouding is tot die grootte van die letsel. Selfs 'n klein seertjie, wat op 'n ander plek onopgemerk sou bly, veroorsaak groot ongerief aan die lyer, veral as dit deur 'n kunsgebit gedruk word. Die probleme wat 'n baba met tandekry ondervind, is ook welbekend. Die behandeling daarvan moet veral toegespits word op spoedige en doeltreffende verligting van pyn deur plaaslike aanwending in plaas van sistemiese behandeling. **TEEJEL GEL** voorsien in hierdie behoefte deur 'n nuwe benadering tot die behandeling van pyn en ongerief in die mond, ongeag die oorsaak. Van die aktiewe bestanddele, is choliensalisilaat 'n hoogs oplosbare en nie-irriterende sout van salisielsuur met 'n kragtige pynstillende en ontstekingswerende werking. Anders as aspirien, kan dit regstreeks aan die slymvliese gebruik word sonder dat dit irritasie veroorsaak. Setalkoniumchloried is 'n wyespektrumkiemdoder met oppervlakte-aktiewe eienskappe. Dit onderdruk Gram-positiewe en Gram-negatiewe bakteriese groei op 'n doeltreffende wyse. Omdat dit die oppervlaktespanning verlaag vergemaklik dit die aanraking van die choliensalisilaat met die aangetaste deel. So, saam gebruik, verskaf hierdie bestanddele vinnige en doeltreffende verligting van pyn en ongemak en bevorder dit spoedige genesing. Talle kliniese proewe het dit bevestig.

INDIKASIES:
Afteuse mondulkusse en ander mondulkusse en ander mondswere en skaafplekke, kunsgebitseertjies, tandvleisontsteking, tongontsteking, sproei, herpes labialis, roulip, letsels aan die neusslymvliese (insluitende die neus- en mondletsels van veelvuldige eriteem en lichen planus) en die tandekry van 'n baba.

KONTRA-INDIKASIES:
Gevoeligheid vir salisilaat.

DOSIS EN GEBRUIKSAANWYSINGS:
Gebruik 'n gewaste vinger of vingerkap en plaas genoeg van die jel (vir volwassenes en ouer kinders word een sentimeter uitgedruk uit die buis, gewoonlik gebruik en vir babas en kinders tot twee jaar, 'n half sentimeter) op die gevoelige deel van die wang of neusslymvlies. Vryf goed in en herhaal die aanwending drie of vier keer per dag voor maaltye en met slaaptyd.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Geen ongunstige reaksie is opgemerk nie. Die effense prikkelende gevoel kan regstreeks aan die alkoholinhoud van die jel toegeskryf word.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Soos vir aspirien. Maagspoeling met simptomatiese en ondersteunende behandeling.

IDENTIFIKASIE:
TEEJEL GEL is 'n kleurlose jel wat gegeur is met anys en mentol. Die naam **TEEJEL GEL** is op die buis gedruk.

AANBIEDING:
5 g buise.

BERGINGSAANWYSINGS:
Bêre benede 25 °C in 'n koel plek. HOU BUITE BEREIK VAN KINDERS.

VERWYSINGSNOMMER:
G2805 (Wet 101/1965)

NAAM EN BESIGHEIDSADRES VAN DIE APPLIKANT:
Adcock Ingram Limited
New Road 1
Erand Gardens
Midrand, 1685
Privaatsak X69
Bryanston, 2021
www.adcock.com

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:
02 Oktober 1979

Onder lisensie van:
Mundipharma A.G., Switserland

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