SCHEDULING STATUS: **S1**

PROPRIETARY NAME: **ADCO-PROLIEF TABLETS**
(AND DOSAGE FORM) **(TABLET)**

COMPOSITION:

Each tablet contains:	
Paracetamol	500, 00 mg
Preservative:	
Nipastat/Salistat (total parabens)	0,124 % m/m
Sugar free	
Contains TARTRAZINE	

PHARMACOLOGICAL CLASSIFICATION:

A 2.7 Antipyretic or antipyretic and anti-inflammatory analgesics

PHARMACOLOGICAL ACTION:

ADCO-PROLIEF TABLETS have analgesic and antipyretic action.

INDICATIONS:

For the relief of mild to moderate pain and fever.

CONTRAINDICATIONS:

Hypersensitivity to paracetamol.

Patients with severe liver function impairment.

WARNINGS:

Consult your doctor if no relief is obtained with the recommended dosage.

Do not use continuously for more than 10 days without consulting your doctor.

Dosage in excess of those recommended may cause severe liver damage.

Patients suffering from liver or kidney disease should take paracetamol under medical supervision.

Store in a safe place out of reach of children.

ADCO-PROLIEF TABLETS contain TARTRAZINE, which may cause allergic type reactions (including bronchial asthma) in certain individuals. The overall incidence of tartrazine sensitivity is low. It is however frequently seen in patients who also have aspirin sensitivity.

DOSAGE AND DIRECTIONS FOR USE:

Adults: One to two tablets every four hours when necessary. (Maximum of 8 tablets in 24 hours)

Children: 6 to 12 years: ½ to 1 tablet every 4 hours when necessary (Maximum of 4 tablets in 24 hours)

Children under 6 years: Not recommended. Paracetamol syrup should rather be considered for use if such a medicine is necessary.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Paracetamol in excess of that recommended may cause severe liver damage. Sensitivity reactions resulting in reversible skin rash or blood disorders such as neutropenia, pancytopenia and leucopenia may occur. The rash is usually erythematous or urticarial but sometimes more serious, and may be accompanied by drug fever and mucosal lesions.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Paracetamol overdosage symptoms in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain, which may persist for a week or more. During the first 2 days of acute poisoning symptoms do not reflect the potential seriousness of the overdosage. Liver injury may become manifest on the second day, (or later) initially by elevation of serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of prothrombin time. The liver damage may progress to encephalopathy, coma and death. Acute renal failure with acute tubular necrosis may develop. Cerebral oedema and nonspecific myocardial depression have also occurred.

Treatment:

In the event of overdosage consult your doctor or take the patient to the nearest hospital immediately. Specialised treatment is essential as soon as possible.

The latest information regarding the treatment of overdosage can be obtained from the nearest poison centre.

Any patient who has ingested about 7,5g of paracetamol in the preceding 4 hours should undergo gastric lavage. Specific therapy with an antidote such as acetylcysteine or methionine may be necessary. If decided upon, acetylcysteine should be administered as soon as possible, preferably IV and within 8 hours of overdosage.

Further treatment is symptomatic and supportive.

IDENTIFICATION:

Yellow, flat tablet, bisected on the one side and plain on the other side.

PRESENTATION:

100, 500, 1 000, 5 000 and 20 000.

STORAGE INSTRUCTIONS:

Store in well-closed containers in a cool place below 25 °C.

Protect from light. Exposure to air should be minimal.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

B/2.7/1259

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

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DATE OF PUBLICATION OF THIS PACKAGE INSERT:

09 September 1991

SKEDULERINGSTATUS: **S1**

EIENDOMSNAAM: **ADCO-PROLIEF TABLETS**
(EN DOSEERVORM) **(TABLET)**

SAMESTELLING:

Elke tablet bevat:	
Parasetamol	500,00 mg
Preserveermiddel:	
Nipastat/Salistat (totale parabene)	0,124 % m/m

Suikervry
Bevat TARTRASIEN

FARMAKOLOGIESE KLASSIFIKASIE:
A 2.7. Antipiretiese of antipiretiese en antiïnflammatoriese analgetika

FARMAKOLOGIESE WERKING:
ADCO-PROLIEF TABLETS besit pynstillende en koorswerende aksie.

INDIKASIES:
Vir die verligting van geringe tot matige pyn en koors.

KONTRA-INDIKASIES:
Hipersensitiwiteit vir parasetamol.
Pasiënte met ernstige lewerverswakking.

WAARSKUWINGS:
Raadpleeg u geneesheer indien geen verligtiging verkry word met die aanbevole dosis nie.
Moet nie vir langer as 10 dae aaneenlopend gebruik word sonder om u geneesheer te raadpleeg nie.
Dosisse wat die aanbevole dosis oorskry kan ernstige lewerskade veroorsaak.
Pasiënte wat aan lewer- of niersiekte ly behoort parasetamol tablette onder mediese toesig te neem.
Bêre in 'n veilige plek buite bereik van kinders.

ADCO-PROLIEF TABLETS bevat TARTRASIEN wat allergie-tipe reaksies kan veroorsaak (insluitend brongiale asma) in sekere vatbare individue. Alhoewel die algemene voorkoms van tartrasiensensitiwiteit in die algemene bevolking huidiglik as laag beskou word, kom dit dikwels voor by pasiënte wat hipersensitief is vir aspirien.

DOSIS EN GEBRUIKSAANWYSINGS:

Volwassenes: Een tot twee tablette elke vier uur wanneer nodig. (Maksimum van 8 tablette in 24 uur).

Kinders 6 tot 12 jaar: ½ tot 1 tablet elke vier uur wanneer nodig, (Maksimum van 4 tablette in 24 uur).

Kinders onder 6 jaar: Nie aanbeveel nie. Parasetamolstroop behoort eerder oorweeg te word indien so 'n medisyne benodig word.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:

Parasetamol wat die aanbevole dosis te bowe gaan kan ernstige lewerskade veroorsaak. Sensitiwiteitsreaksies wat omkeerbare veluitslag of bloedafwykings soos neutrofieltekort, allebloedselafname of witbloedseltekort insluit, kan voorkom. Die uitslag is gewoonlik eritemateus of netelroosagtig maar soms meer ernstig en kan deur geneesmiddelkoors en slymvliesbeserings vergesel wees.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Simptome van parasetamoloordosering wat binne 24 uur voorkom sluit in bleekheid, naarheid, braking, aptytverlies en buikpyn, wat vir 'n week of meer kan volhou. Simptome gedurende die eerste twee dae van akute vergiftiging kan nie die moontlike erns die oordosering weerspieël nie. Lewerbesering kan op die tweede dag verskyn (of later) aanvanklik deur verhoging van serumtransaminase- en laktiese dehidrogenase-aktiwiteit, verhoogde serumbilirubienkonsentrasie en verlenging van protrombientyd. Die lewerbesering kan tot enkefalopatie, koma en dood lei. Akute nierversaking met akute tubulêre nekrose kan voorkom. Serebrale edeem en nie-spesifieke hartspieronderdrukking kan ook voorkom.

Behandeling:

In die geval van oordosering, raadpleeg u geneesheer of neem die pasiënt onmiddellik na die naaste hospitaal. Gespesialiseerde behandeling is noodsaaklik as gou as moontlik. Die jongste inligting met betrekking tot die behandeling van oordosering kan van die naaste vergiftingsentrum verkry word.
Enige pasiënt wat omtrent 7,5 g parasetamol binne die voorafgaande 4 uur ingeneem het moet maagspoeling ondergaan. Spesifieke terapie met 'n teenmiddel soos asetielsisteïen of metionien kan nodig wees. As ‘n besluit geneem is, moet asetielsisteïen so gou as moontlik toegedien word, verkieslik intraveneus en binne 8 uur van oordosering.
Verdere behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:

Geel, plat tablette, gehalveer aan die een kant en gewoon aan die ander kant.

AANBIEDING:

100, 500, 1 000, 5 000 en 20 000.

BERGINGSAANWYSINGS:

Bêre in diggeslote houers in 'n koel plek onder 25 ºC. Beskerm teen lig. Blootstelling aan lug moet minimaal wees.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:

B/2.7/1259

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIE-SERTIFIKAAT:

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