SCHEDULING STATUS: S0

PROPRIETARY NAME: PANADO® PAEDIATRIC SYRUP ALCOHOL AND SUGAR FREE
PANADO® PAEDIATRIC SYRUP
(AND DOSAGE FORM) (SYRUP)

COMPOSITION:

PANADO PAEDIATRIC SYRUP ALCOHOL AND SUGAR FREE:

Each 5 ml syrup contains:

Paracetamol	120 mg

Preservatives:

Benzoic acid	0,30 % m/v
Potassium sorbate	0,10 % m/v

Contains no tartrazine.

PANADO PAEDIATRIC SYRUP:

Each 5 ml syrup contains:

Paracetamol	120 mg

Preservatives:

Methylparaben	0,10 % m/v
Ethanol	10 % v/v

Contains sugar:

Glucose	2,5 g
Sucrose	807 mg

Contains no tartrazine.

PHARMACOLOGICAL CLASSIFICATION:

A 2.7 Antipyretic or antipyretic and anti-inflammatory analgesics.

PHARMACOLOGICAL ACTION:

Paracetamol has analgesic and antipyretic actions.

INDICATIONS:

For the relief of mild to moderate pain and fever.

CONTRA-INDICATIONS:

Hypersensitivity to paracetamol.
Severe liver function impairment.

WARNINGS:

Dosages in excess of those recommended may cause severe liver damage.
Patients suffering from liver or kidney disease should take paracetamol under medical supervision.
Consult a doctor if no relief is obtained with the recommended dosage.
Do not use continuously for more than 10 days without consulting a doctor.

DOSAGE AND DIRECTIONS FOR USE:

Children:	6 - 12 years	10 - 20 ml
	1 - 5 years	5 - 10 ml
Infants:	3 months - 1 year	2,5 - 5 ml

Repeat dosage every 6 - 8 hours if necessary, but not more than 4 doses in 24 hours.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Skin rashes and other allergic reactions may occur. The rash is usually erythematous or urticarial but sometimes more serious and may be accompanied by fever and mucosal lesions. The use of paracetamol has been associated with the occurrence of neutropenia, pancytopenia and leucopenia.

Special precautions:

1. Consult a doctor if no relief is obtained from the recommended dosage.
2. Store in a safe place out of reach of children.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or poison control centre must be contacted immediately.

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias have been reported.

Symptoms during the first 2 days of acute poisoning do not reflect the potential seriousness of the overdosage. Nausea, vomiting, anorexia and abdominal pain may persist for a week or more. 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. Cerebral oedema and non-specific myocardial depression have also occurred. 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. Prompt treatment is essential. Any patient who has ingested about 7,5 g 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 IV as soon as possible.

Acetylcysteine:
Acetylcysteine should be administered as soon as possible, preferably within 8 hours of overdosage.
IV: An initial dose of 150 mg/kg in 200 ml glucose injection, given intravenously over 15 minutes, followed by an intravenous infusion of 50 mg/kg in 500 ml glucose injection over the next 4 hours and then 100 mg/kg in 1 000 ml over the next 16 hours. The volume of intravenous fluids should be modified for children. Orally: 140 mg/kg as a 5 % solution initially, followed by a 70 mg/kg solution every 4 hours for 17 doses. Acetylcysteine is effective if administered within 8 hours of overdosage.

IDENTIFICATION:

PANADO PAEDIATRIC SYRUP ALCOHOL AND SUGAR FREE:
Sweet, peppermint flavoured, green syrup.

PANADO PAEDIATRIC SYRUP:
Peppermint flavoured, green syrup.

PRESENTATION:

PANADO PAEDIATRIC SYRUP ALCOHOL AND SUGAR FREE:
Clear glass bottles of 50 ml, 100 ml and clear PVC bottles of 50 ml and 100 ml.

PANADO PAEDIATRIC SYRUP:
Clear glass bottles of 50 ml, 100 ml and clear PVC bottles of 50 ml and 100 ml.

STORAGE INSTRUCTIONS:

Store below 25 ºC in a well closed container protected from light. Exposure to air should be kept to a minimum.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS:

PANADO PAEDIATRIC SYRUP ALCOHOL AND SUGAR FREE: V/2.8/208
PANADO PAEDIATRIC SYRUP: B/2.7/1143

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

Adcock Ingram Limited
3011 William Nicol Drive
Bryanston
Private Bag X69
Bryanston 2021
www.adcock.co.za

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
25 January 1995

SKEDULERINGSTATUS: **S0**

EIENDOMSNAAM: **PANADO® PAEDIATRIC SYRUP ALCOHOL AND SUGAR FREE**
PANADO® PAEDIATRIC SYRUP
(EN DOSEERVORM) **(STROOP)**

SAMESTELLING:

PANADO PAEDIATRIC SYRUP ALCOHOL AND SUGAR FREE:

Elke 5 ml stroop bevat:

Parasetamol	120 mg

Preserveermiddels:

Bensoësuur	0,30 % m/v
Kaliumsorbaat	0,10 % m/v

Bevat geen tartrasien.

PANADO PAEDIATRIC SYRUP:

Elke 5 ml stroop bevat:

Parasetamol	120 mg

Preserveermiddels:

Metielparabeen	0,10 % m/v
Etanol	10 % v/v

Bevat suiker:

Glukose	2,5 g
Sukrose	807 mg

Bevat geen tartrasien.

FARMAKOLOGIESE KLASSIFIKASIE:

A 2.7 Antipiretiese of antipiretiese en antiïnflammatoriese analgetikum.

FARMAKOLOGIESE WERKING:

Parasetamol het pynstillende en koorswerende werkings.

INDIKASIES:

Vir die verligting van ligte tot matige pyn en koors.

KONTRA-INDIKASIES:

Oorgevoeligheid vir parasetamol.
Ernstige lewerfunksiebeskadiging.

WAARSKUWINGS:

Dosisse hoër as wat aanbeveel word, kan ernstige lewerskade veroorsaak.
Pasiënte wat aan lewer- of niersiektes ly, moet parasetamol onder mediese toesig gebruik.
Raadpleeg 'n dokter indien geen verligting met die aanbevole dosis verkry word nie.
Moet nie langer as 10 dae aaneenlopend gebruik sonder om 'n geneesheer te raadpleeg nie.

DOSIS EN GEBRUIKSAANWYSINGS:

Kinders:	6 - 12 jaar	10 - 20 ml
	1 - 5 jaar	5 - 10 ml
Babas:	3 maande - 1 jaar	2,5 - 5 ml

Herhaal dosis elke 6 - 8 uur indien nodig, maar nie meer as 4 dosisse in 24 uur nie.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:

Veluitslag en ander sensitiwiteitsreaksies kan voorkom. Die uitslag is gewoonlik eritemateus of urtikaries, maar kan soms ernstiger wees en gepaard gaan met koors en mukosale letsels. Met die gebruik van parasetamol kan neutropenie, pansitopenie en leukopenie voorkom.

Spesiale voorsorgmaatreëls:

1. Raadpleeg 'n geneesheer indien verligting nie verkry word met aanbevole dosis nie.
2. Bêre in 'n veilige plek buite bereik van kinders.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

In die geval van oordosering of vermoedelike oordosering en ondanks die feit dat die persoon dalk asimptomaties is, moet die naaste geneesheer, hospitaal of gifhulpsentrum onmiddellik geraadpleeg word.

Simptome van parasetamoloordosering in die eerste 24 uur is bleekheid, naarheid, braking, anoreksie en abdominale pyn. Simptome van lewerskade kan 12 tot 48 uur na inname na vore tree. Abnormaliteit van glukosemetabolisme en metaboliese asidose kan voorkom. Akute nierversaking met akute tubulêre nekrose kan ontwikkel, selfs in die afwesigheid van ernstige lewerskade. Hartaritmieë is gerapporteer.

Tydens die eerste 2 dae van akute vergiftiging word die potensiële erns van die oordosering nie deur die simptome uitgewys nie. Naarheid, braking, anoreksie en buikpyn kan vir 'n week of langer voortduur.

Lewerbeskadiging kan na die tweede dag (of later) na vore tree, eerstens deur verhoging van serumstransaminase- en laktaatdehidrogenase-aktiwiteit, verhoogde serumbilirubienkonsentrasie en verlengde protrombientyd. Lewerbeskadiging kan aanleiding gee tot enkefalopatie, koma en die dood. Serebrale edeem en nie-spesifieke miokardiale onderdrukking het ook voorgekom.

In die geval van oordosering, raadpleeg u geneesheer of neem die pasiënt onmiddellik na die naaste hospitaal. Gespesialiseerde behandeling is so spoedig moontlik noodsaaklik. Onmiddellike behandeling is noodsaaklik. Enige pasiënt wat ongeveer 7,5 g parasetamol in die voorafgaande 4 uur ingeneem het moet 'n maagspoeling ondergaan. Spesifieke terapie met 'n teenmiddel soos asetielsisteïen of metionien kan nodig wees. Indien daarop besluit word, moet asetielsisteïen so gou moontlik binneaars toegedien word.

Asetielsisteïen:

Asetielsisteïen moet so spoedig moontlik toegedien word, verkieslik binne 8 ure na oordosering. Binneaars: 'n Aanvanklike dosis van 150 mg/kg in 200 ml glukose-inspuiting binneaars toegedien oor 15 minute gevolg deur 'n binneaarse infusie van 50 mg/kg in 500 ml glukose-inspuiting oor die daaropvolgende 4 uur, daarna 100 mg/kg in 1 000 ml versprei oor die volgende 16 uur. Die volume van binneaarse vloeistowwe moet vir kinders aangepas word.

Mondeliks: Aanvanklik 140 mg/kg as 'n 5 % oplossing gevolg deur 'n 70 mg/kg oplossing elke 4 uur vir 17 doserings. Asetielsisteïen is doeltreffend indien dit binne 8 uur na oordosering toegedien word.

IDENTIFIKASIE:

PANADO PAEDIATRIC SYRUP ALCOHOL AND SUGAR FREE:
Soet, peperment-gegeurde, groen stroop.

PANADO PAEDIATRIC SYRUP:
Peperment-gegeurde, groen stroop.

AANBIEDING:

PANADO PAEDIATRIC SYRUP ALCOHOL AND SUGAR FREE:
Deurskynende glasbottels met 50 ml, 100 ml en deurskynende PVC bottels met 50 ml en 100 ml.

PANADO PAEDIATRIC SYRUP:
Deurskynende glasbottels met 50 ml, 100 ml en deurskynende PVC bottels met 50 ml en 100 ml.

BERGINGSAANWYSINGS:

Bêre benede 25 ºC in diggeslote houer en beskerm teen lig. Blootstelling aan lug moet tot 'n minimum beperk word.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMERS:

PANADO PAEDIATRIC SYRUP ALCOHOL AND SUGAR FREE: V/2.8/208
PANADO PAEDIATRIC SYRUP: B/2.7/1143

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT :

Adcock Ingram Limited

William Nicolrylaan 3011
Bryanston
Privaatsak X69
Bryanston
www.adcock.co.za

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:
25 Januarie 1995