

SCHEDULING STATUS: **S0**

PROPRIETARY NAME: **PANADO® INFANT DROPS**
(and dosage form) **(Drops)**

COMPOSITION:

Each 0,6 ml contains:

Paracetamol 60 mg

Preservatives:

Methylparaben 0,085% m/v

Propylparaben 0,015 % m/v

Sugar free.

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:

Infants: 3 months - 1 year 0,6 - 1,2 ml

Repeat dosage 4 hourly 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 N-

acetylcysteine or methionine may be necessary. If decided upon, N-acetylcysteine should be administered IV as soon as possible.

N-acetylcysteine:

N-acetylcysteine should be administered as soon as possible, preferably within 8 hours of overdose.

IV: An initial dose of 150 mg/kg in 200 ml dextrose injection, given intravenously over 15 minutes, followed by an intravenous infusion of 50 mg/kg in 500 ml dextrose 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.

N-acetylcysteine is effective if administered within 8 hours of overdose.

IDENTIFICATION:

Sweet, peppermint flavoured, green syrup.

PRESENTATION:

20 ml Clear glass bottle with closure and a calibrated dropper.

STORAGE INSTRUCTIONS:

Store in a well closed container protected from light. Store below 25 °C. Exposure to air should be kept to a minimum.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

V/2.7/209

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE REGISTRATION

CERTIFICATE:

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

QA Amendment
Sugar and layout
09/03/2007

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

August 1990

SKEDULERINGSSTATUS: S0

EIENDOMSNAAM: **PANADO® INFANT DROPS**
(en doseervorm) **(Druppels)**

SAMESTELLING:

Elke 0,6 ml bevat:

Parasetamol 60 mg

Preserveermiddels:

Metielparabeen 0,085 % m/v

Propielparabeen 0,015 % m/v

Suikervry

FARMAKOLOGIESE KLASSIFIKASIE:

A 2.7 Antipiretiese of antipiretiese en antiïflammatoriese 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 lewerfunksie beskadiging.

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:

Babas: 3 maande - 1 jaar 0,6 - 1,2 ml

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

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:

Veluitslag en ander sensitiviteitsreaksies 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 die 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 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 N-asetielsisteïen of metionien kan nodig wees. Indien daarop besluit word, moet N-asetielsisteïen so gou moontlik binnears toegedien word.

N-asetielsisteïen:

N-asetielsisteïen moet so spoedig moontlik toegedien word, verkieslik binne 8 ure na oordosering. Binnears: 'n Aanvanklike dosis van 150 mg/kg in 200 ml dekstrose-inspuiting binnears toegedien oor 15 minute gevolg deur 'n binnearse infusie van 50 mg/kg in 500 ml dekstrose-inspuiting oor die daaropvolgende 4 uur, daarna 100 mg/kg in 1 000 ml versprei oor die volgende 16 uur. Die volume van binnearse 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. N-asetielsisteïen is doeltreffend indien dit binne 8 uur na oordosering toegedien word.

IDENTIFIKASIE:

Soet mentgegeurde, groen stroop.

AANBIEDING:

20 ml Deurskynende glasbottel met 'n prop en 'n gekalibreerde drupper.

BERGINGSAAWYSINGS:

Bêre in 'n diggeslote houer en beskerm teen lig. Benede 25 °C. Blootstelling aan lug moet tot 'n minimum beperk word.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:

V/2.7/209

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

Adcock Ingram Limited
William Nicolrylaan 3011
Bryanston
Privaatsak X69
Bryanston, 2021
www.adcock.co.za

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET: Augustus 1990

FACSIMILE OF LABEL

	<p>20 ml</p> <p>Paracetamol 60 mg/0,6 ml</p> <p>PANADO* INFANT DROPS</p> <p>For relief of mild to moderate pain and fever</p> <p>LOGO</p>	
	<p>Each 0,6 ml contains: paracetamol 60 mg, methylparaben 0,085% m/v and propylparaben 0,015% m/v preservatives./Elke 0,6 ml bevat: parasetamol 60 mg, metielparaben 0,085% m/v en propielparaben 0,015% m/v as preserveermiddels.</p> <p>Dosage: Infants: 3 months - 1 year: 0,6-1,2 ml. Repeat dosage 4 hourly if necessary, but not more than 4 doses in 24 hours./Dosering: Babas: 3 maande - 1 jaar: 0,6-1,2 ml. Herhaal dosis elke 4 uur indien nodig, maar nie meer as 4 dosisse in 24 uur nie.</p>	
	<p>20 ml</p> <p>Parasetamol 60 mg/0,6 ml</p> <p>PANADO* INFANT DROPS</p> <p>Vir verligting van ligte tot matige pyn en koors</p> <p>LOGO</p>	

Warning: Do not use continuously for more than 10 days without consulting your doctor. Store below 25 °C. Protect from light and air.

KEEP OUT OF REACH OF CHILDREN.

Waarskuwing: Moenie langer as 10 dae aaneenlopend gebruik sonder om u geneesheer te raadpleeg nie. Bêre benede 25 °C. Beskerm teen lig en lug. **HOU BUIE BEREIK VAN KINDERS.**

Contains paracetamol - read package insert Bevat prasetamol - lees voubiljet
--

Adcock Ingram Limited
17 Harrison Ave
Bryanston
2021

V/2.7/209	*Reg. T.M./Gereg. H.m.	Mapics Number
Batch/Lot:		Expires/Verval: