

SCHEDULING STATUS: **S0** – Pack sizes with less than 25 capsules
S1 – Pack sizes with or more than 25 capsules

PROPRIETARY NAME: **PANADO® CAPSULES**
(AND DOSAGE FORM) **(CAPSULE)**

COMPOSITION:
Each capsule contains 500 mg paracetamol.
Sugar free.

PHARMACOLOGICAL CLASSIFICATION:
A 2.8 Non-narcotic analgesics, antipyretics.

PHARMACOLOGICAL ACTION:
Paracetamol has analgesic and antipyretic actions.

INDICATIONS:
For the relief of mild to moderate pain and fever such as headaches, toothache and pain associated with colds and flu.

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

DOSAGE AND DIRECTIONS FOR USE:
Adults: One or two capsules repeated every 3–4 hours if necessary, but not more than 8 capsules to be taken in any 24 hour period.
Children 9–12 years: One capsule repeated every 3–4 hours if necessary, but not more than 4 doses in any 24 hour period.
Children under 9 years: Not recommended.

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:
A hard gelatin capsule, size No. 0 opaque white body and cap, with "Panado 500" printed in red.

PRESENTATION:
Blister packs of 20 and 30 sealed capsules.

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

REGISTRATION NUMBER:
S/2.8/57

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:
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PREPRESS CUSTOMER APPROVAL

Repro Ticket	43170
File Number	ADCP613a
Customer	ADCOCK INGRAM
Product	PANADO CAPSULES PACKAGE INSERT
Code	104263 08/2007
Flat Size	L 260 W 120
Folded Size	L 32 W 120
Pharma Code	73
Colours	BLACK
Proof No	5
Date	11/09/2007
Operator	JK
Proof Reader	

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...Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.

- Make amendments as indicated and supply another proof.
- Make amendments and proceed.
- APPROVED – Please proceed.**

Approved by	
Signature	
Date	

SKEDULERINGSTATUS: **S0** – Verpakkings met minder as 25 kapsules
S1 – Verpakkings met of meer as 25 kapsules

EIENDOMSNAAM: **PANADO® CAPSULES**
(EN DOSEERVORM) **(KAPSULE)**

SAMESTELLING:
Elke kapsule bevat 500 mg parasetamol.
Suikervry.

FARMAKOLOGIESE KLASSIFIKASIE:
A 2.8 Nie-narkotiese analgetika, antipiretika.

FARMAKOLOGIESE WERKING:
Parasetamol het pynstillende en koorswerende werkings.

INDIKASIES:
Vir die verligting van ligte tot matige pyn en koors soos hoofpyn, tandpyn en pyn geassosieer met verkoue en griep.

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.
Moet nie langer as 10 dae aaneenlopend gebruik sonder om 'n geneesheer te raadpleeg nie.

DOSIS EN GEBRUIKSAANWYSINGS:
Volwasse nes: Een of twee kapsules. Herhaal elke 3–4 uur indien nodig, maar nie meer as 8 kapsules binne enige 24 uur periode nie.
Kinders 9–12 jaar: Een kapsule. Herhaal elke 3–4 uur indien nodig, maar nie meer as 4 dosisse binne enige 24 uur periode nie.
Kinders onder 9 jaar: Nie aanbeveel nie.

NEWE-EFFEKTE EN SPESIALE VOORSORGMATREËLS:
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 gifhulpentrum 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 metabiese asidose kan voorkom.
Akute nierversaking met akute tubulêre nekrose kan ontwikkel selfs in die afwesigheid van ernstige lewerskade. Hartaritmieë is vermeld.

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 serumtransaminase- en laktaatdehidrogenase-aktiwiteit, verhoogde serumbilirubin-konsentrasie 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 asetielisteien of metionien kan nodig wees. Indien daarop besluit word, moet asetielisteien so gou moontlik IV toegedien word.

Asetielisteien:
Asetielisteien moet so spoedig moontlik toegedien word, verkieslik binne 8 ure na oordosering.
Binnears: 'n Aanvanklike dosis van 150 mg/kg in 200 ml glukose-inspuiting binnears toegedien oor 15 minute gevolg deur 'n binnearse 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 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.
Asetielisteien is doeltreffend indien dit binne 8 uur na oordosering toegedien word.

IDENTIFIKASIE:
'n Harde gelatienkapsule, grootte Nr. 0, wit opaak liggaam en dop met "Panado 500" in rooi gedruk.

AANBIEDING:
Stolpverpakkings van 20 en 30 verseëelde kapsules.

BERGINGS- AANWYSINGS:
Bêre benede 25 °C in 'n diggeslote houër en beskerm teen lig. Blootstelling aan lug moet tot 'n minimum gehou word.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIONOMMER:
S/2.8/57

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
Adcock Ingram Limited
William Nicolrylaan 3011
Bryanston
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Bryanston, 2021
www.adcock.co.za

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