SCHEDULING STATUS: S0

PROPRIETARY NAME: **COMPRAL HEADACHE TABLETS**

(AND DOSAGE FORM) **(TABLET)**

COMPOSITION:
Each tablet contains:

Paracetamol	100 mg
Aspirin	400 mg
Caffeine anhydrous	30 mg

Sugar free
List of excipients: Acacia, starch corn, purified talc, hydrogenated cottonseed oil, sodium lauryl sulphate, colloidal silicon dioxide, microcrystalline cellulose, purified water.

PHARMACOLOGICAL CLASSIFICATION:
A: 2.8 Analgesic combinations

PHARMACOLOGICAL ACTION:
COMPRAL HEADACHE TABLETS have analgesic, anti-inflammatory and antipyretic actions. They inhibit the biosynthesis of prostaglandins.

INDICATIONS:
COMPRAL HEADACHE TABLETS are effective for the relief of pain of mild to moderate intensity and is also indicated in a wide variety of febrile conditions.

CONTRAINDICATIONS:
Patients with peptic ulcers, haemophilia, intolerance (hypersensitivity) to any of the active ingredients, severe renal impairment or patients receiving oral anticoagulant therapy.

WARNINGS:
Aspirin has been implicated in Reye's Syndrome, a rare but serious illness, in children and teenagers with chicken pox or influenza. A doctor should be consulted before aspirin is used in such patients.
Not to be taken during the first and third trimesters of pregnancy except under the advice and supervision of a medical doctor.
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.
Excessive and prolonged use of this medicine may be dangerous.

DOSAGE AND DIRECTIONS FOR USE:
Adults: 1 to 2 tablets, 4 hourly.
Children 6 to 12 years: ½ to 1 tablet, 4 hourly.
Children under 6 years: as prescribed by a physician.
Not more than 4 doses in 24 hours.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:
Paracetamol:
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.
Aspirin:
Dizziness or irritation of the gastric mucosa and resultant dyspepsia, haematemesis, and melaena may occur in some cases. Some persons, especially asthmatics exhibit notable sensitivity to aspirin which may include skin eruptions, paroxysmal bronchospasm and dyspnoea. It should be administered with caution to patients with impaired renal function, dyspepsia, anaemia and when patients are dehydrated. Aspirin may enhance the activity of coumarin anticoagulants, oral antidiabetic preparations and sulphonamides. Aspirin diminishes the effects of antigout preparations such as probenecid and sulphinpyrazone. Barbiturates and other sedatives may mask the respiratory symptoms of aspirin overdosage and have been reported to enhance its toxicity. Prolonged use of high doses may lead to anaemia, blood dyscrasias, gastrointestinal haemorrhage, peptic ulceration and renal papillary necrosis.
The use of aspirin in the first and third trimesters of pregnancy is not advised.
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.

Paracetamol:
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 dextrose injection, given intravenously over 15 minutes, followed by an intravenous infusion of 50 mg/kg in 500 ml of 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. Acetylcysteine is effective if administered within 8 hours of overdosage.
Aspirin:
Symptoms include dizziness, tinnitus, sweating, nausea, vomiting, mental confusion, hyperventilation, respiratory alkalosis, metabolic acidosis, ketosis and depression of the central nervous system. In children serious signs of overdosage may develop rapidly.

IDENTIFICATION:
White, scored, bevel-edged tablets with the word **"COMPRAL"** imprinted on one side.

PRESENTATION:
2 polypaper strips of 2 tablets each packed in a carton, polypaper strips of 2 tablets, blister packs containing 12, 24, 36 or 72 tablets, and tracer packs of 50 and 100 tablets.

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

REGISTRATION NUMBER:
B/2.8/1147

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

adcock ingram

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SKEDULERINGSTATUS: S0

EIENDOMSNAAM: **COMPRAL HEADACHE TABLETS**

(EN DOSEERVORM) **(TABLET)**

SAMESTELLING:
Elke tablet bevat:

Parasetamol	100 mg
Aspirien	400 mg
Watervrye kafeïen	30 mg

Suikervry
Lys van bymiddels: Akasia, mieliestylsel, gesuiwerde talk, gehidreerde katoenpitolie, natriumlourielsulfaat, koloïdale silikoondioksied, mikrokristallyne sellulose, gesuiwerde water.

FARMAKOLOGIESE KLASSIFIKASIE:
A: 2.8 Analgetiese samestellings

FARMAKOLOGIESE WERKING:
COMPRAL HEADACHE TABLETS het pynstillende, anti-inflammatoriese en koorswerende werkings. Dit strem die biosintese van prostaglandiene.

INDIKASIES:
COMPRAL HEADACHE TABLETS is doeltreffend vir die verligting van pyn van ligte tot matige intensiteit en is ook aangedui in 'n wye verskeidenheid van koorstoestande.

KONTRA-INDIKASIES:
Pasiënte met peptiese ulkusse, hemofilie, of onverdraagsaamheid (hipersensitiwiteit) teenoor enige van die aktiewe bestanddele, ernstige nierversaking of pasiënte wat mondelike antistolterapie ontvang.

WAARSKUWINGS:
Aspirien is geïmpliseer in Reye-sindroom, 'n skaars maar ernstige siekte, onder kinders en tienderjariges wat waterpokkies of griep het. 'n Dokter behoort geraadpleeg te word voordat aspirien aan sulke pasiënte toegedien word.
Moet nie gebruik gedurende die eerste en derde trimesters van swangerskap nie tensy op advies en onder toesig van 'n geneesheer.
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.
Oormatige en langdurige gebruik van hierdie medisyne kan gevaarlik wees.

DOSIS EN GEBRUIKSAANWYSINGS:
Volwassenes: 1 tot 2 tablette, elke 4 uur.
Kinders 6 tot 12 jaar: ½ tot 1 tablet, elke 4 uur.
Kinders onder 6 jaar oud: soos voorgeskryf deur 'n geneesheer.
Nie meer as 4 dosisse in 24 uur nie.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Parasetamol:
Veluitslae en ander allergiese reaksies 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.
Aspirien:
Duiseligheid of irritasie van die maagslymvliese en gevolglike dispepsie, hematemese en melena kan voorkom in sommige gevalle. Sommige persone, veral asmalyers, openbaar 'n merkbare sensitiwiteit teenoor aspirien wat veluitslag, paroksismale brongospasme en dispnee kan insluit. Dit behoort met versigtigheid toegedien te word aan pasiënte met nierwanfunksie, dispepsie, anemie en wanneer die pasiënt gedehidreer is. Aspirien kan die aktiwiteit van kumarienantistolmiddels, mondelike antidiabetiese middels en sulfoonamiede verhoog. Aspirien verminder die effekte van antijig middels soos probenesied en sulfienpirasoon. Barbiturate en ander kalmeermiddels kan die respiratoriese simptome van aspirienoordosering verberg en daar is aangemeld dat dit die toksisiteit van aspirien verhoog. Langdurige gebruik of hoë dosisse kan lei tot anemie, bloedsiektes, gastroïntestinale bloeding, peptiese ulserasie en nierpapillêre nekrose.
Die gebruik van aspirien word nie aanbeveel gedurende die eerste en derde trimesters van swangerskap nie.
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 onmiddellik geraadpleeg word.

Parasetamol:
Simptome van parasetamoloordosering in die eerste 24 uur is bleekheid, naarheid, braking, anoreksie en abdominale pyn. Lewerskade kan 12 tot 48 uur na inname na vore tree. Abnormaliteite van glukosemetabolisme en metaboliese asidose kan voorkom.
Akute nierversaking met akute tubulêre nekrose kan ontwikkel selfs in die afwesigheid van ernstige lewerskade. Hartaritmieë is aangemeld. Tydens die eerste 2 dae van akute vergiftiging word die potensiële erns van die oordosering nie deur die simptome getoon 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 laktaatdehidrogenaseaktiwiteit, verhoogde serumbilirubienkonsentrasie en verlengde protrombientyd. Lewerbeskadiging kan aanleiding gee tot enkefalopatie, koma en die dood. Serebrale edeem en niespesifieke 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 intraveneus 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 'n 200 ml dekstrose-inspuiting binneaars toegedien oor 15 minute gevolg deur 'n binneaarse 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 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.
Aspirien:
Simptome sluit in duiseligheid, oorsuising, sweet, naarheid, braking, geestesverwarring, hiperventilasie, respiratoriese alkalose, metaboliese bloedversuring, ketose en onderdrukking van die sentrale senuweestelsel. By kinders kan ernstige tekens van oordosering baie gou ontwikkel.

IDENTIFIKASIE:
Wit, gegroefde, afgeskuinste tablette met die woord **"COMPRAL"** ingedruk op een kant.

AANBIEDING:
2 polipapierstrokies van 2 tablette elk verpak in 'n karton, polipapierstrokies van 2 tablette, stolpverpakkings bevattende 12, 24, 36 of 72 tablette, en "tracer packs" van 50 en 100 tablette.

BERGINGSAANWYSINGS:
Bêre benede 25 °C in 'n houer wat goed toegemaak is. Blootstelling aan lug moet tot 'n MINIMUM gehou word.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:
B/2.8/1147

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

adcock ingram

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