SCHEDULING STATUS: S0 Pack sizes of 38 or smaller
S1 Pack sizes larger than 38

PROPRIETARY NAME: (AND DOSAGE FORM) # COMPRAL HEADACHE POWDERS (POWDER)

COMPOSITION:
Each powder contains:

Paracetamol	324,0 mg
Aspirin	453,6 mg
Caffeine	64,8 mg

Sugar free.

PHARMACOLOGICAL CLASSIFICATION:
A 2.8 Analgesic combinations

PHARMACOLOGICAL ACTION:
COMPRAL HEADACHE POWDERS has analgesic, antipyretic and anti-inflammatory properties.

INDICATIONS:
For the symptomatic relief of mild to moderate pain such as headaches, dysmenorrhoea (painful menstrual period), pain in muscles and joints, dental pain, colds or flu and fever.

CONTRAINDICATIONS:
Hypersensitivity (allergy) to paracetamol or to aspirin.
Should not be administered to patients with gout; haemophilia (inherited bleeding disorder) or other haemorrhagic disorders; severe renal or hepatic impairment; patients prone to dyspepsia (heartburn) or known to have a lesion of the gastric mucosa; or patients taking anticoagulants (substance to stop blood from clotting).

WARNINGS:

Do not exceed the recommended dosage. In event of overdosage and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or poison control centre must be contacted immediately.

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.
Aspirin has been implicated in Reye's syndrome, a rare but serious illness, in children and teenagers with chickenpox and influenza.
A doctor should be consulted before aspirin is used in such patients.
Not to be taken during the last 3 months of pregnancy unless ordered by your doctor.
Use during lactation (breast-feeding) is not recommended.
Aspirin should be discontinued several days before scheduled surgical procedures.

DOSAGE AND DIRECTIONS FOR USE:
Not recommended for children under the age of 12 years.
Adults: One powder to be taken after a meal with water. May be repeated every four hours, if necessary.
Do not exceed six powders per day.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:
Aspirin: Gastrointestinal disturbances such as nausea, dyspepsia (heartburn) and vomiting; may cause dizziness or irritation of the gastric mucosa with erosion, ulceration, haematemesis (vomiting of blood), and melaena (blood in stools).
Some persons, especially those with asthma, exhibit notable sensitivity to aspirin which may provoke various hypersensitivity (allergic) reactions which may include skin eruptions, paroxysmal bronchospasm (episodic wheezing due to narrowing of the air pipes), dyspnoea (difficulty in breathing) and shock. Aspirin increases bleeding time.
Less frequent: Reyes syndrome in children, agranulocytosis, thrombocytopenia, aplastic anaemia.
Paracetamol: Skin rashes and other allergic reactions may occur. The rash is usually erythematous (red skin rash) or urticarial (allergic skin rash), but sometimes more serious and may be accompanied by fever and mucosal lesions. Haematological reactions, including thrombocytopenia, leucopenia, pancytopenia, neutropenia and agranulocytosis have been reported.
Caffeine: Nausea, vomiting, increase in gastric acid secretion, headache, insomnia (inability to sleep), anxiety, restlessness, tachycardia (increased rate of heartbeat) and quickened respiration.

Precautions:
Aspirin: It should be administered with caution to patients with renal and hepatic malfunction; dyspepsia (heartburn) or known to have a lesion of the gastric mucosa; asthma or allergic disorders; anaemia; patients with glucose-6-phosphate dehydrogenase deficiency; diabetics; when the patient is dehydrated and in the presence of uncontrolled high blood pressure. Prolonged use of high doses may lead to gastrointestinal haemorrhage, peptic ulceration (stomach and duodenal ulcers) and renal papillary necrosis.
Paracetamol: Should be given with care to patients with impaired kidney and liver function and patients with alcohol dependence.
Caffeine: With prolonged use some degree of tolerance and psychological dependence may occur. This product must be taken with care by persons with a history of peptic ulceration (stomach and duodenal ulcers).

INTERACTIONS:
Aspirin: Aspirin may enhance the activity of coumarin anticoagulants and sulphonylurea hypoglycaemic drugs, methotrexate, phenytoin, and valproic acid. 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.
Paracetamol: The risk of paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce liver microsomal enzymes such as carbamazepine, phenytoin, phenobarbitone and rifampicin. The absorption of paracetamol may be accelerated by metoclopramide. Cholestyramine reduces the absorption of paracetamol if given within one hour of paracetamol administration. Excretion may be affected when administered with probenecid.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Aspirin: These include dizziness, tinnitus (ringing in the ears), deafness, sweating, nausea, vomiting, headache, mental confusion, hyperventilation, fever, restlessness, respiratory alkalosis, metabolic acidosis, ketosis and depression of the central nervous system which may lead to coma.
Paracetamol: Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia (lack of appetite) and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion.
Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac abnormalities and pancreatitis have been reported.
Symptoms during the first 2 days of acute poisoning do not reflect the potential seriousness of the overdosage. Nausea, vomiting, anorexia (lack of appetite) and abdominal pain may persist for a week or more. Clinical indications of hepatic damage become manifest within 2 to 4 days, by elevation of plasma aminotransferases, increased serum bilirubin concentration and prolongation of prothrombin time. The liver damage may progress to encephalopathy, coma and death. Complications of hepatic failure include acidosis, cerebral oedema, haemorrhage, hypoglycaemia, hypotension, infection, renal failure.
In the event of overdosage consult a doctor or take the patient to the nearest hospital immediately. Specialised treatment is essential as soon as possible. Gastric lavage should be performed in all cases, preferably within 4 hours of the ingestion. Antidote therapy with acetylcysteine or methionine should be started as soon as possible after suspected paracetamol ingestion.
N-Acetylcysteine: N-Acetylcysteine (antidote of choice) is most effective when administered intravenously during the first 8 hours following ingestion of the overdose.
Intravenous infusion: 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 of 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.
Oral administration: 140 mg/kg as a 5 % solution initially, followed by a 70 mg/kg solution every 4 hours for 17 doses.
Caffeine: Insomnia, restlessness, excitement are the early signs, which may progress to mild delirium, emesis (vomiting) and convulsions. Muscle tremor, tachycardia (increased rate of heartbeat) and extra systoles (abnormal heartbeat) are frequent, and respiration is quickened.

IDENTIFICATION:
A fine, white, crystalline powder with a slight acidic odour and very bitter taste.

PRESENTATION:
845 mg of powder packed in polypaper sachets in packs of 10, 24, 38, 48 and in single doses.

STORAGE INSTRUCTIONS:
Store in airtight containers, protected from light, below 25 °C.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
36/2.8/0009

NAME AND 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

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SKEDULERINGSTATUS: S0 Pakgroottes van 38 en kleiner
S1 Pakgroottes van meer as 38

EIENDOMSNAAM:
(EN DOSEERVORM)

COMPRAL HEADACHE POWDERS (POEIER)

SAMESTELLING:
Elke poeier bevat:

Parasetamol	324,0 mg
Aspirien	453,6 mg
Kafeïen	64,8 mg

Suikervry.

FARMAKOLOGIESE KLASSIFIKASIE:
A 2.8 Analgetiese samestellings

FARMAKOLOGIESE WERKING:
COMPRAL HEADACHE POWDERS het pynstillende, antipiretiese (koorswerende) en anti-inflammatoriese eienskappe.

INDIKASIES:
Vir die simptomatiese verligting van ligte tot matige pyn soos hoofpyn, dismenoree (pynlike menstruasie), pyn in spiere en gewrigte, tandpyn, verkoue, griep en koors.

KONTRA-INDIKASIES:
Word teenaangedui by pasiënte wat hipersensitief (allergies) vir parasetamol en aspirien is.
Moet nie toegedien word aan pasiënte wat aan jig, hemofilie (oorerflike bloedingsteurnis) en ander hemoragiese afwykings ly nie, ernstige renale of hepatiese inkorting, asook pasiënte geneig tot dispepsie (sooibrand) of wat 'n letsel van die gastriese (maag) mukosa het of pasiënte wat met antistolmiddels behandel word.

WAARSKUWINGS:

Moet nie die voorgeskrewe daaglikse dosis oorskry nie. In die geval van oordosering, ondanks die feit dat die persoon asimptomaties mag wees, moet die naaste dokter, hospitaal of gifkontrolesentrum onmiddellik gekontak word.

Dosisse wat die voorgeskrewe hoeveelhede oorskry kan ernstige lewerskade veroorsaak.
Pasiënte wat aan lewer- of nierkwale ly moet parasetamol onder mediese toesig neem.
Moenie langer as 10 dae gebruik word sonder om 'n geneesheer te raadpleeg nie.
Aspirien is al geassosieer met Reye-sindroom in kinders, 'n seldsame maar ernstige siekte wat in kinders en tieners met waterpokkies en griep voorkom.
'n Geneesheer moet geraadpleeg word voordat aspirien aan hierdie pasiënte toegedien word.
Moet nie gedurende die laaste 3 maande van swangerskap gebruik word nie, tensy anders deur die geneesheer voorgeskryf word.
Die gebruik tydens borsvoeding word nie aanbeveel nie.
Die gebruik van aspirien moet etlike dae voor 'n chirurgiese prosedure gestaak word.

DOSIS EN GEBRUIKSAANWYSINGS:
Nie aanbeveel vir kinders onder die ouderdom van 12 jaar nie.
Volwassenes: Neem een poeier met water na 'n maaltyd. Kan elke vier uur herhaal word, indien nodig.
Moenie meer as ses poeiers per dag gebruik nie.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Aspirien: Gastroïntestinale steurnisse soos naarheid, dispepsie (sooibrand) en vomering; kan duiseligheid of irritasie van die gastriese (maag) mukosa met erosie, ulserasie, hematemese (vomering van bloed) en melaena (bloed in stoelgang) veroorsaak.
Sekere individue, veral asmalyers, toon duidelike sensitiwiteit vir aspirien wat verskeie allergiese reaksies kan veroorsaak wat veluitslag, 'n hewige aanval van brongospasma (episodiese hyging/gefluit as gevolg van die vernouing van die lugpyp), dispnee en skok insluit.
Aspirien verhoog die bloedingstydperk.
Minder gereeld: Reye-sindroom in kinders, agranulositose, trombositopenie, aplastiese anemie.
Parasetamol: Veluitslag en ander allergiese reaksies mag voorkom. Die uitslag is gewoonlik eritemateus (rooi veluitslag) of urtikaries (allergiese veluitslag) maar somtyds meer ernstig en kan gepaard gaan met koors en mukosale letsels. Hematologiese reaksies, insluitende trombositopenie, leukopenie, pansitopenie, neutropenie en agranulositose is al aangemeld.
Kafeïen: Naarheid, vomering, verhoging in gastriese suursekresie, hoofpyn, insomnia (slaaploosheid), angstigheid, rusteloosheid, tagikardie (verhoogde hartklop) en verhoogde respirasie.

Voorsorgmaatreëls:
Aspirien: Moet met sorg toegedien word aan pasiënte met nier- en hepatiese wanfunksies; dispepsie (sooibrand) of wat geneig is tot letsels van die gastriese mukosa; asma of allergiese afwykings; anemie; pasiënte met glukose-6-fosfaat dehidrogenase wanfunksie; diabete; en as die pasiënt gedehidreer is en aan ongekontroleerde hoë bloeddruk ly. Verlengde gebruik van hoë dosisse kan tot gastroïntestinale bloeding, peptiese ulserering (maag en duodenale ulkusse) en renale papilêre nekrose lei.
Parasetamol: Moet met sorg toegedien word aan pasiënte met verswakte nier- en lewerfunksies en pasiënte wat aan alkohol verslaaf is.
Kafeïen: Met gebruik oor die langtermyn kan 'n mate van toleransie en psigologiese afhanklikheid voorkom. Die produk moet met sorg geneem word deur pasiënte met 'n geskiedenis van peptiese ulserasies (maag- en duodenale ulkusse).

INTERAKSIES:
Aspirien: Aspirien kan die aktiwiteit van kumarien-antikoagulante en sulfonielurea hipoglukemiese middels, metotreksaat, fenitoïen en valproësuur verhoog. Aspirien verminder die effek van antijig preparate soos probenesied en sulfienpirasoon. Barbiturate en ander kalmeermiddels kan die respiratoriese simptome van 'n oordosis aspirien verberg en dit is al aangemeld dat dit die toksisiteit verhoog.
Parasetamol: Die risiko van parasetamoltoksisiteit kan verhoog word in pasiënte wat behandel word met ander potensiële hepatotoksiese middels of middels wat lewer-mikrosomale ensieme induseer soos karbamasepien, fenitoïen, fenobarbitoon en rifampisien. Die absorpsie van parasetamol kan bespoedig word deur metoklopramied. Cholestiramien verminder die absorpsie van parasetamol indien geneem word binne 'n uur vanaf die inname van parasetamol. Ekskresie kan geaffekteer word as parasetamol tesame met probenesied toegedien word.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Aspirien: Sluit in duiseligheid, tinnitus (gesuis in ore), gehoorverlies, sweetafskeiding, naarheid, braking, hoofpyn, begripsverwarring, hiperventilasie, koors, rusteloosheid, respiratoriese alkalose, metaboliese asidose, ketose en onderdrukking van die sentrale senuweestelsel, wat tot 'n koma kan lei.
Parasetamol: Simptome van parasetamoloordosering gedurende die eerste 24 uur, sluit in, bleekheid, naarheid, braking, anoreksie (eetlusverlies) en abdominale pyn. Lewerskade kan binne 12 tot 48 uur na inname sigbaar word.
Akute nierversaking met akute tubulêre nekrose kan ontwikkel, selfs in die afwesigheid van ernstige lewerskade. Kardiale abnormaliteite en pankreatitis is al aangemeld.
Simptome tydens die eerste 2 dae van akute vergiftiging, reflekteer nie die potensiële erns van die oordosis nie. Naarheid, braking, anoreksie (eetlusverlies) en abdominale pyn kan vir 'n week of meer voortduur. Kliniese indikasies van hepatiese skade kan binne 2 tot 4 dae manifesteer, deur die verhoging van plasma-aminotransferases, verhoogde serumbilirubienkonsentrasie en verlenging van die protrombientyd. Die lewerskade kan tot enkefalopatie, koma en die dood lei. Komplikasies van lewerversaking sluit asidose, serebrale edeem, hemoragie (bloeding), hipoglukemie, hipotensie, infeksie en nierversaking in.
In die geval van oordosering raadpleeg 'n geneesheer of neem die pasiënt onmiddellik na die naaste hospitaal. Gespesialiseede behandeling is noodsaaklik, so gou as moontlik. Maagspoeling moet in alle gevalle geïnduseer word, verkieslik binne 4 uur na inname. Teenmiddelterapie met asetielsisteïen of metionien moet so gou as moontlik na die inname van parasetamol begin.
N-Asetielsisteïen: N-Asetielsisteïen (teenmiddel van keuse) is mees effektief as dit binneaars binne die eerste 8 uur van inname van die oordosis toegedien word.
Intraveneuse infusie: 'n Aanvangsdosis van 150 mg/kg in 200 ml glukose-inspuiting binneaars gegee oor 'n tydperk van 15 minute, gevolg deur binneaarse infusie van 50 mg/kg in 'n 500 ml glukose-inspuiting oor die volgende 4 uur, en dan 100 mg/kg in 1 000 ml wat oor die volgende 16 uur gegee word. Die volume van intraveneuse vloeistowwe moet vir kinders aangepas word.
Orale toediening: 140 mg/kg as 'n 5 % oplossing aanvanklik, gevolg deur 'n 70 mg/kg oplossing elke 4 uur vir 17 dosisse.
Kafeïen: Insomnia (slaaploosheid), rusteloosheid en opgewondenheid is vroeë tekens, wat kan ontwikkel tot matige delirium, emese (braking) en stuiptrekkings. Spiertrillings, tagikardie (verhoogde hartklop), en ekstrasistole (abnormale hartkloppings) kom gereeld voor en asemhaling is verhoog.

IDENTIFIKASIE:
'n Fyn, wit, kristallyne poeier met 'n effe suur reuk en 'n baie bitter smaak.

AANBIEDING:
845 mg poeier verpak in 'n polipapiersakkie in pakke van 10, 24, 38, 48 en in enkel verpakkings.

BERGINGSAANWYSINGS:
Bêre in lugdigte houer. beskerm teen lig, benede 25 °C.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:
36/2.8/0009

NAAM EN ADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
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William Nicolrylaan 3011
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