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

PROPRIETARY NAME (AND DOSAGE FORM): **COMPRAL PAIN POWDERS (POWDER)**

COMPOSITION:
Each sachet of powder contains:

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

Sugar free.
Excipient: Colloidal Anhydrous Silica

PHARMACOLOGICAL CLASSIFICATION:
A 2.8 - Analgesic combinations

PHARMACOLOGICAL ACTION:
COMPRAL PAIN 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 and inflammation, colds or flu and fever.

CONTRA-INDICATIONS:
Intolerance or hypersensitivity to aspirin or other NSAIDs, paracetamol, caffeine or to any of the ingredients of **COMPRAL PAIN POWDERS.**
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).
Active or history of recurrent ulcer/haemorrhage/perforations.
Heart failure
History of gastrointestinal perforation, ulceration or bleeding (PUBs) related to previous NSAIDs, including **COMPRAL PAIN POWDERS.**
COMPRAL PAIN POWDERS must not be used in children or teenagers under 18 years of age.

WARNINGS AND SPECIAL PRECAUTIONS:

This product contains paracetamol which may be fatal in overdose.
In event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.

Dosages in excess of those recommended may cause severe liver damage.
Paracetamol should be given with care to patients with impaired kidney and liver function and patients with alcohol dependence.
Patients suffering from liver or kidney disease should take paracetamol under medical supervision.
Do not use continuously for more than 10 days without consulting your 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 for use in children and adolescents under 18 years of age.
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 administered with caution to patients with renal and hepatic malfunction or known to have a lesion of the gastric mucosa; asthma or allergic disorders; anaemia; patients with glucose 6-phosphate dehydrogenase deficiency; and when the patient is dehydrated. Prolonged use of high doses may lead to renal papillary necrosis.
Caution is required in patients with a history of hypertension and/or heart failure as fluid retention and oedema have been reported in association with **COMPRAL PAIN POWDERS** therapy. In view of the **COMPRAL PAIN POWDERS** inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.
Elderly: The elderly have an increased frequency of adverse reactions to NSAIDs including **COMPRAL PAIN POWDERS**, especially gastrointestinal perforation, ulceration and bleeding (PUBs) which may be fatal.
The risk of gastrointestinal perforation, ulceration or bleeding (PUBs) is higher with increasing doses of **COMPRAL PAIN POWDERS**, in patients with a history of ulcers, and the elderly.
When gastrointestinal bleeding or ulceration occurs in patients receiving **COMPRAL PAIN POWDERS**, treatment with **COMPRAL PAIN POWDERS** should be stopped.
COMPRAL PAIN POWDERS should be given with caution to patients with a history of gastrointestinal disease (e.g. ulcerative colitis, Crohn's disease, hiatus hernia, gastro-oesophageal reflux disease, angiodysplasia) as the condition may be exacerbated.
Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolyis have been reported. **COMPRAL PAIN POWDERS** should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.
Regular use of NSAIDs such as **COMPRAL PAIN POWDERS** during the third trimester of pregnancy, may result in premature closure of the foetal ductus arteriosus *in utero*, and possibly, in persistent pulmonary hypertension of the new-born. The onset of labour may be delayed and its duration increased.
Aspirin should be discontinued several days before scheduled surgical procedures.
Caffeine: With prolonged use some degree of tolerance and psychological dependence may occur.

INTERACTIONS:
Aspirin: Aspirin may enhance the activity of 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.
NSAIDs: use of two or more NSAIDs concomitantly could result in an increase in side effects.
Corticosteroids: increased risk of gastrointestinal perforation, ulceration or bleeding (PUBs).
Anti-coagulants: **COMPRAL PAIN POWDERS** may enhance the effects of anti-coagulants such as warfarin.
Anti-platelet medicines and selective serotonin reuptake inhibitors (SSRIs): increased risk of gastrointestinal bleeding.
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.

PREGNANCY AND LACTATION
Safety and efficacy in pregnancy and lactation have not been established.
Pregnancy
Not to be taken during the last 3 months of pregnancy unless ordered by your doctor.
Lactation
Use during lactation (breast-feeding) is not recommended.

DOSAGE AND DIRECTIONS FOR USE:
DO NOT EXCEED THE RECOMMENDED DOSE
Use the lowest effective dose for the shortest possible duration of treatment.
Not for use in children and adolescents under the age of 18 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.

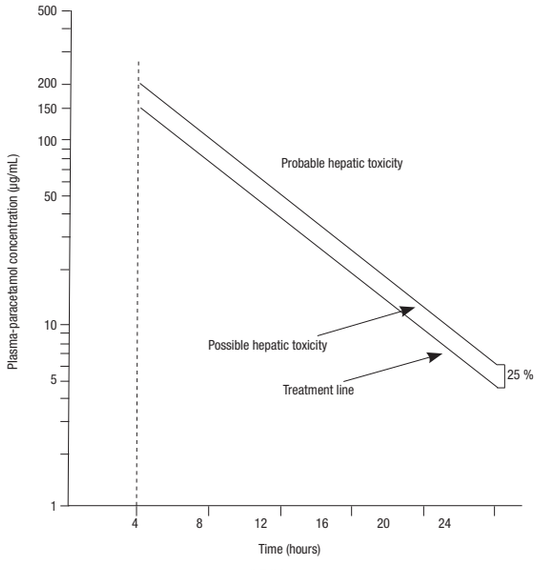
SIDE EFFECTS:
Aspirin: Gastrointestinal disturbances such as nausea, dyspepsia (heartburn) and vomiting; may cause dizziness or irritation of the gastric mucosa with erosion, ulceration, haematemesis (vomiting of blood), and melaena (blood in stools).
Some persons especially those with asthma exhibit 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: Reye's syndrome in children, agranulocytosis, thrombocytopenia, aplastic anaemia.
Cardiac disorders:
Oedema, hypertension and cardiac failure.
Gastrointestinal system disorders:
The most commonly observed adverse events are gastrointestinal in nature. Peptic ulcers, perforation or gastrointestinal bleeding, sometimes fatal. Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease, gastritis.
Skin and subcutaneous tissue disorders:
Bullous reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis.

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.

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:
Prompt treatment is essential. In the event of an overdosage, consult a doctor immediately, or take the person directly to a hospital. A delay in starting treatment may mean that antidote is given too late to be effective. Evidence of liver damage is often delayed until after the time for effective treatment has lapsed.
Susceptibility to paracetamol toxicity is increased in patients who have taken repeated high doses (greater than 5 - 10 g/day) of paracetamol for several days, in chronic alcoholism, chronic liver disease, AIDS, malnutrition, and with the use of drugs that induce liver microsomal oxidation such as barbiturates, isoniazid, rifampicin, phenytoin and carbamazepine.
Symptoms of paracetamol overdosage in the first 24 hours include pallor, nausea, vomiting, anorexia and possibly abdominal pain. Mild symptoms during the first two days of acute poisoning, do not reflect the potential seriousness of the overdosage.
Liver damage may become apparent 12 to 48 hours, or later after ingestion, initially by elevation of the serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of the prothrombin time. Liver damage may lead to encephalopathy, coma and death.
Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Abnormalities of glucose metabolism and metabolic acidosis may occur. Cardiac arrhythmias have been reported.
Treatment for paracetamol overdosage:
Although evidence is limited it is recommended that any adult person who has ingested 5 - 10 grams or more of paracetamol (or a child who has had more than 140 mg/kg) within the preceding four hours, should have the stomach emptied by lavage (emesis may be adequate for children) and a single dose of 50 g activated charcoal given via the lavage tube. Ingestion of amounts of paracetamol smaller than this may require treatment in patients susceptible to paracetamol poisoning (see above). In patients who are stuperose or comatose endotracheal intubation should precede gastric lavage in order to avoid aspiration.
N-acetylcysteine should be administered to all cases of suspected overdose as soon as possible preferably within eight hours of overdosage, although treatment up to 36 hours after ingestion may still be of benefit, especially if more than 150 mg/kg of paracetamol was taken. An initial dose of 150 mg/kg N-acetylcysteine in 200 ml dextrose injection given intravenously over 15 minutes, followed by an infusion of 50 mg/kg in 500 ml dextrose injection over the next four hours, and then 100 mg/kg in 1 000 ml dextrose injection over the next sixteen hours. **The volume of intravenous fluid should be modified for children.**
Although the oral formulation is not the treatment of choice, 140 mg/kg dissolved in water may be administered initially, followed by 70 mg/kg every four hours for seventeen doses.
A plasma paracetamol level should be determined four hours after ingestion in all cases of suspected overdosage. Levels done before four hours, may be misleading. Patients at risk of liver damage, and hence requiring continued treatment with N-acetylcysteine, can be identified according to their 4-hour plasma paracetamol level.
The plasma paracetamol level can be plotted against time since ingestion in the nomogram below.
The nomogram should be used only in relation to a single acute ingestion.



Source: Martindale: The Complete Drug Reference - 37th Edition.

Those whose plasma paracetamol levels are above the "normal treatment line", should continue N-acetylcysteine treatment with 100 mg/kg IV over sixteen hours repeatedly until recovery. Patients with increased susceptibility to liver damage as identified above, should continue treatment if concentrations are above the "high risk treatment line". Prothrombin index correlates best with survival.
Monitor all patients with significant ingestions for at least ninety six hours.

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 extrasystoles (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 2, 10, 24, 38, 48 and in single doses.

STORAGE INSTRUCTIONS:
Store in airtight containers, protected from light at or 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
1 New Road
Erand Gardens
Midrand, 1685
Private Bag X69
Bryanston 2021
www.adcock.com

adcock ingram

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
20/09/2002

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Botswana: BOT0801428 S4

30615 01/2019

SKEDULERINGSTATUS: S0 Verpakkingsgroottes van 38 of kleiner S1 Verpakkingsgroottes groter as 38

EIENDOMSNAAM:
(EN DOSEERVORM)

COMPRAL® PAIN POWDERS (POEIER)

SAMESTELLING:
Elke sakkie poeier bevat:

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

Suikervry.
Bymiddel: Kolloïdale watervrye silika

FARMAKOLOGIESE KLASSIFIKASIE:
A 2.8 Analgetiese samestellings

FARMAKOLOGIESE WERKING:
COMPRAL PAIN POWDERS het analgetiese, koorswerende en antiïnflammatoriese eienskappe.

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

KONTRA-INDIKASIES:
Onverdraagsaamheid of oorgevoeligheid teenoor aspirien of ander NSAIMs, parasetamol, kaffeïen of enige van die bestanddele van **COMPRAL PAIN POWDERS.**
Moenie toegedien word nie aan pasiënte met jig, hemofilie (oorerflike bloedingsiekte), of ander bloedingsaandoenings, ernstige nier of lewerbelemmering; pasiënte wat geneig is om aan slegte spysvertering (sooibrand) te ly of bekend is om 'n letsel van die maagslymvliese te hê; of pasiënte wat teenstollingsmedikasie (middels wat verhoed dat bloedklonte vorm) gebruik.
Aktiewe of geskiedenis van terugkerende ulkusse/bloeding/perforasies.
Hartversaking.
Geskiedenis van gastroïntestinale perforasie, ulserasie of bloeding (PUBs) verbind met vorige NSAIMs, insluitende **COMPRAL PAIN POWDERS.**
COMPRAL PAIN POWDERS moet nie in kinders en adolessente jonger as 18 jaar gebruik word nie.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:

Hierdie produk bevat parasetamol wat noodlottig kan wees in die geval van oordosering. In die geval van 'n oordosering of vermoedelike oordosering en ondanks die feit dat die person dalk asimptomaties is, moet die naaste geneesheer, hospitaal of Gifhulpsentrum onmiddellik geraadpleeg word.

Dosisse wat hoër is as dié wat aanbeveel is, kan ernstige lewerskade veroorsaak.
Parasetamol moet met omsigtigheid toegedien word aan pasiënte met belemmering van die nier en lewerfunksies en aan pasiënte met alkoholafhanklikheid.
Pasiënte wat aan lewer of niersiektes ly moet parasetamol slegs onder mediese toesig gebruik.
Moet nie langer as10 dae gebruik sonder om 'n geneesheer te raadpleeg nie.
Aspirien is geïmpliseer in Reye's-sindroom, 'n seldsame maar ernstige siekte, onder kinders en tienderjariges wat waterpokkies of griep het. 'n Dokter moet geraadpleeg word voordat aspirien in sulke pasiënte gebruik word. Moet nie by kinders en adolessente onder 18 jaar oud, gebruik nie.
Moenie gebruik tydens die laaste 3 maande van swangerskap nie, tensy op die dokter se instruksies.
Gebruik tydens laktasie (borsvoeding) word nie aanbeveel nie.
Aspirien moet met omsigtigheid toegedien word aan pasiënte met nier en lewerwanfunksie of dié wat bekend is om 'n letsel van die maagslymvliese te hê, asma of allergiese aandoenings; anemie; pasiënte met glukose 6-fosfaat dehidrogenasetekort; en wanneer die pasiënt gedehidreerd is. Verlengde gebruik van hoë dosisse kan lei tot renale papillêre nekrose.
Omsigtigheid word geverg in pasiënte met 'n geskiedenis van hipertensie en/of hartversaking aangesien vloeistofretensie en edeem vermeld is in verband met **COMPRAL PAIN POWDERS** behandeling. In die lig van die **COMPRAL PAIN POWDERS** se inherente potensiaal om vloeistofretensie te veroorsaak, kan hartversaking aangebring word in sommige gekompromiteerde pasiënte.
Bejaardes: Bejaardes het 'n toenemende voorkomsfrekwensie van ongunstige reaksies teenoor NSAIMs, insluitende **COMPRAL PAIN POWDERS**, veral gastroïntestinale perforasie, ulserasie en bloeding (PUBs) wat noodlottig kan wees.
Die risiko vir gastroïntestinale perforasie, ulserasie of bloeding (PUBs) is hoër met toenemende dosisse van **COMPRAL PAIN POWDERS**, in pasiënte met 'n geskiedenis van ulkusse en in bejaardes.
Sou gastroïntestinale bloeding of ulserasie voorkom in pasiënte wat **COMPRAL PAIN POWDERS** ontvang, moet behandeling met **COMPRAL PAIN POWDERS** gestaak word.
COMPRAL PAIN POWDERS met omsigtigheid gegee word aan pasiënte met 'n geskiedenis van gastroïntestinale siekte (bv. ulseratiewe kolitis, Crohn se siekte, hiatus hernia, gastroësofageale reflukssiekte, angiodisplasie) aangesien die toestand kan vererger.
Ernstige velreaksies, sommige noodlottig, insluitend eksfoliatiewe dermatitis, Stevens-Johnson- sindroom, en toksiese epidermale nekrolise is vermeld. **COMPRAL PAIN POWDERS** moet onttrek word by die eerste verskyning van veluitslag, mukosale letsels, of enige ander teken van hipersensitiwiteit.
Gereelde gebruik van NSAIMs soos **COMPRAL PAIN POWDERS** gedurende die derde trimester van swangerskap, mag lei tot die premature sluiting van die fetale ductus arteriosus *in utero*, en moontlik, in volgehoue pulmonale hipertensie by die pasgeborene. Die aanvang van kraam mag vertraag wees en die duur daarvan mag verleng wees.
Aspirien behoort verskeie dae voor geskeduleerde chirurgiese prosedures gestaak te word. **Kaffeïen:** Met verlengde gebruik mag 'n mate van toleransie en psigologiese afhanklikheid ontwikkel.

INTERAKSIES:
Aspirien
Aspirien mag die werking van sulfonielurea hipoglisemiese geneesmiddels, metotreksaat, fenitoïen en valproësuur versterk. Aspirien verlaag die werkings van teenjigpreparate soos probenesien en sulfienpirasoon. Barbiturate en ander kalmeermiddels mag die respiratoriese simptome van aspirienoordosering verberg en daar is vermeld dat dit die toksisiteit van aspirien verhoog.
NSAIMs: meegaande gebruik van twee of meer NSAIMs kan lei tot 'n verhoging in newe-effekte.
Kortikosteroïede: verhoogde risiko vir gastroïntestinale perforasie, ulserasie of bloeding (PUBs).
Teenstollingsmiddels: **COMPRAL PAIN POWDERS** kan die werking van teenstollingsmiddels soos warfarien versterk.
Anti-plaatjiemiddels en selektiewe serotonien-heropname-remmers (SSRIs): verhoogde risiko vir gastroïntestinale bloeding.
Parasetamol: Die risiko vir parasetamoltoksisiteit kan verhoog wees by pasiënte wat ander potensiële hepatotoksiese geneesmiddels ontvang of ander geneesmiddels wat lewer- mikrosomale ensieme opwek soos karbamasepien, fenitoïen, fenobarbitoon en rifampisien. Die absorpsie van parasetamol kan versnel word deur metoklopramied. Cholestiramien verlaag die absorpsie van parasetamol indien dit geneem word binne een uur vanaf parasetamoltoediening. Uitskeiding kan geaffekteer word indien dit saam met probenesied toegedien word.

SWANGERSKAP EN LAKTASIE:
Veiligheid en doeltreffendheid tydens swangerskap en laktasie is nog nie vasgestel nie.
Swangerskap
Moet nie gebruik gedurende derde trimester van swangerskap nie, tensy op advies en onder die toesig van 'n geneesheer.
Laktasie
Gebruik tydens laktasie (borsvoeding) word nie aanbeveel nie.

DOSIS EN GEBRUIKSAANWYSINGS:
MOENIE DIE AANBEVOLE DOSIS OORSKRY NIE
Gebruik die laagste doetreffende dosis vir die kortste moontlike tydperk van behandeling.
Nie vir gebruik by kinders en adolessente jonger as 18 jaar nie.
Volwassenes: Een poeier geneem na 'n maaltyd saam met water. Kan elke vier uur herhaal word, indien nodig. Moenie ses poeiers per dag oorskry nie.

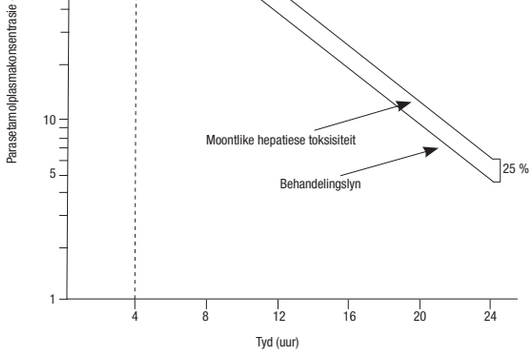
NEWE-EFFEKTE:
Aspirien: Gastroïntestinale versteurings soos naarheid, slegte spysvertering (sooibrand) en braking; kan duiseligheid veroorsaak of irritasie van die maagslymvliese met erosie, ulserasie, hematemese (braking van bloed), en melena (bloed in stoelgang).
Party mense, veral dié wat aan asma ly, vertoon merkbare sensitiwiteit teenoor aspirien wat verskeie hipersensitiwiteit (allergiese) reaksies kan ontketen soos velerupsies, paroksismale brongospasma (episodiese hyging te wyte aan vernouing van die lugpype), en asemnood (moeilikheid om asem te haal) en skok. Aspirien verhoog bloedingtyd.
Minder dikwels: Reye's-sindroom in kinders, agranulositose, trombositopenie, aplastiese anemie.
Kardiale aandoenings
Edeem, hipertensie en hartversaking.
Gastroïntestinale aandoenings
Die mees algemene ongunstige effekte wat waargeneem is, is gastroïntestinaal van aard. Peptiese ulkusse, perforasie of gastroïntestinale bloeding, soms noodlottig. Naarheid, braking, diaree, winderigheid, hardlywigheid, slegte spysvertering, buikpyn, melena, hematemese, ulseratiewe stomatitis, verergering van kolitis en Crohn se siekte, gastritis.
Vel- en onderhuidseweefselaandoenings
Bulleuse reaksies, insluitend Stevens-Johnson-sindroom en toksiese epidermale nekrolise.

Parasetamol:
Veluitslae en ander allergiese reaksies mag voorkom. Die uitslag is gewoonlik eritemateus (rooi veluitslag) of urtikaries (allergiese veluitslag) van aard, maar soms meer ernstig en kan gepaard wees met koors en mukosale letsels.
Hematologiese reaksies, insluitend trombositopenie, leukopenie, pansitopenie, neutropenia en agranulositose is vermeld.

Kaffeïen: Naarheid, braking, verhoogde gastriese uitskeiding, hoofpyn, insomnie (onvermoë om te slaap/slaaploosheid), angs, rusteloosheid, tagikardie (verhoogde hartslagtempo) en versnelde asemhaling.

BEKENDE SIMPTOME VAN OORDOSIS EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN
Aspirien:
Simptome sluit in duiseligheid, oorsuising, doofheid, sweet, naarheid, braking, hoofpyn, geestesverwarring, hiperventilasie, koors, rusteloosheid, respiratoriese alkalose, metaboliese bloedversuring, ketose en onderdrukking van die sentrale senuweestelsel wat mag lei tot koma.

Parasetamol:
Onmiddellike behandeling is essensieel. In die geval van 'n oordosering, raadpleeg 'n geneesheer onmiddellik of neem die pasiënt dadelik na die naaste hospitaal. 'n Vertraging in die instelling van behandeling, kan beteken dat die teenmiddel te laat gegee word om effektief te wees. Bewyse van lewerskade is dikwels vertraag, totdat die tyd vir effektiewe behandeling verby is.
Vatbaarheid vir parasetamoltoksisiteit is verhoog by pasiënte wat herhaalde hoë dosisse (meer as 5 tot 10 g/dag) van parasetamol oor verskeie dae geneem het, in chroniese alkoholisme, chroniese lewersiekte, VIGS, wanvoeding en met die gebruik van geneesmiddels wat lewermikrosomale oksidasie kan aanbring, soos barbiturate, isoniasied, rifampisien, fenitoïen en karbamasepien.
Simptome van parasetamoloordosering in die eerste 24 uur, sluit in bleekheid, naarheid, braking, anoreksie en moontlik abdominale pyn. Ligte simptome gedurende die eerste twee dae van akute vergiftiging weerspieël nie die potensiële erns van die oordosering nie.
Lewerskade mag na 12 tot 48 uur, of selfs later, na inname waarneembaar wees, aanvanklik as verhoogde serumtransaminase- en melksuurdehidrogenase-aktiwiteit, verhoogde serumbilirubien-konsentrasie en verlenging van die protrombientyd. Die lewerskade mag tot enkefalopatie, koma en die dood lei.
Akute nierversaking met akute, tubulêre nekrose mag selfs in die afwesigheid van ernstige lewerskade ontstaan. Abnormaliteite van glukosemetabolisme en metaboliese asidose mag voorkom. Hartaritmieë is vermeld.
Behandeling van parasetamoloordosering:
Alhoewel bewyse daarvan beperk is, word dit aanbeveel dat enige volwasse persoon wat 5 tot 10 gram of meer parasetamol ingeneem het, (of 'n kind wat meer as 140 mg/kg ingeneem het) binne die voorafgaande vier ure, se maag geledig moet word deur 'n maagspoeling (emese mag voldoende wees by kinders) en 'n enkeldosis van 50 g geaktiveerde koolstof via die lavagebuis gegee word. Pasiënte wat vatbaar is vir parasetamolvergiftiging (sien hierbo), mag behandeling benodig indien kleiner hoeveelhede van parasetamol as dié, ingeneem is. By pasiënte wat bedwelmd is of in 'n koma is, moet endotrageale intubasie voor gastriese lavage gedoen word, om sodoende aspirasie te voorkom.
N-asetielsisteïen moet so gou as moontlik toegedien word by alle gevalle van 'n vermoedelike oordosis, verkieslik binne agt ure na die oordosis, alhoewel behandeling tot en met 36 uur na inname steeds voordelig kan wees, veral indien meer as 150 mg/kg parasetamol ingeneem is. 'n Aanvangsdosis van 150 mg/kg N-asetielsisteïen in 'n 200 ml dekstrose-inspuiting, binneaars toegedien oor 'n 15 minute tydperk, gevolg deur 'n intraveneuse infusie van 50 mg/kg in 500 ml dekstrose-inspuiting, oor die volgende vier ure en dan 100 mg/kg in 1 000 ml dekstrose-inspuiting oor die volgende sestien ure. **Die volume van die intraveneuse vloeistowwe moet aangepas word vir kinders.**
Alhoewel die orale formulering nie die behandeling van keuse is nie, kan 140 mg/kg opgelos in water aanvanklik toegedien word, gevolg deur 'n 70 mg/kg oplossing elke vier ure vir sewentien doserings. 'n Parasetamol-plasmavlak moet bepaal word vier ure na inname in alle gevalle van 'n vermoedelike oordosis. Vlakke wat gemeet word voor 4 ure kan misleidend wees. Pasiënte wat die risiko loop van lewerskade, en daarom ook voortgaande behandeling benodig met N-asetielsisteïen, kan geïdentifiseer word volgens hulle 4-uur parasetamol-plasmavlakke.
Die parasetamol-plasmavlakke kan teen tyd vanaf inname grafies voorgestel word in die nomogram hieronder.
Die nomogram behoort slegs gebruik te word met betrekking tot 'n enkele akute inname.



Bron: Martindale: The Complete Drug Reference - 37ste Uitgawe.

Pasiënte wie se parasetamol-plasmavlakke bo die normale behandelingslyn is, moet voortgaan met N-asetielsisteïenbehandeling van 100 mg/kg IV oor sestien uur, wat herhaal moet word tot herstel. Pasiënte met 'n verhoogde vatbaarheid vir lewerskade soos hierbo geïdentifiseer, moet met die behandeling voortgaan indien konsentrasies bo die hoërisiko behandelingslyn voorkom. Protrombien-indeks korreleer die beste met oorlewing.
Moniteer alle pasiënte wat 'n beduidende hoeveelheid ingeneem het vir ten minste ses-en-negentig uur.

Kaffeïen: Insomnie, rusteloosheid, opgewondenheid is die vroeë tekens, wat mag lei tot ligte ylhoofdigheid, emese (braking) en stuiptrekkings. Spierbewing, tagikardie (verhoogde hartslagtempo) en ekstrasistolieë (abnormale hartslag) is algemeen en versnelde asemhaling.

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

AANBIEDING:
845 mg poeier word verpak in polipapiersakkies in pakke van 2, 10, 24, 38, 48 en in enkeldosisse.

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

REGISTRASIENOMMER:
36/2.8/0009

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