

SCHEDULING STATUS

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COMPRAL® PAIN TABLETS

Paracetamol 100 mg, Aspirin 400 mg, and Caffeine anhydrous 30 mg
Sugar free

Read all of this leaflet carefully because it contains important information for you.

COMPRAL® PAIN TABLETS is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use COMPRAL® PAIN TABLETS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share COMPRAL® PAIN TABLETS with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

1. What COMPRAL® PAIN TABLETS is and what it is used for
2. What you need to know before you take COMPRAL® PAIN TABLETS
3. How to take COMPRAL® PAIN TABLETS
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1. What COMPRAL® PAIN TABLETS is and what it is used for

COMPRAL® PAIN TABLETS belongs to a group of medicines called analgesic combinations, used to relieve pain. COMPRAL® PAIN TABLETS is used for the relief of pain of mild to moderate intensity and is also indicated in a wide variety of febrile conditions (related to fever).

2. What you need to know before you take COMPRAL® PAIN TABLETS

Do not take COMPRAL® PAIN TABLETS:

- if you have or ever had a problem of your blood not clotting properly, have severe liver function problems or if you are taking medicines to reduce blood clotting.
- if you are hypersensitive (allergic) to aspirin or other NSAIDs, paracetamol, caffeine or to any of the other ingredients of COMPRAL® PAIN TABLETS. (listed in section 6).
- if you have a history of asthma, bronchospasm (sudden constrictions of the muscles of the passage ways by which air passes through the nose to the air sacs of the lungs), angioedema (painless swelling of the tissue layer under the skin), rhinitis (irritation and inflammation of the mucous membranes inside the nose), urticaria (hives), when you take aspirin or non-steroidal anti-inflammatory drugs (NSAIDs-class of medicines which aspirin belongs to).
- if you have or ever had a stomach ulcer, damage or bleeding of the stomach related to previous use of aspirin and other NSAIDs (class of medicines which aspirin belongs to) including COMPRAL® PAIN TABLETS.
- if you have severe kidney damage, liver impairment or heart failure.
- if you have or ever had gout.
- if you are pregnant, do not use NSAIDs at 30 weeks or later in your pregnancy because these medicines may cause problems in your unborn baby.
- If you have a history of intestine rupture, open wounds or bleeding related to NSAIDS, including COMPRAL® PAIN TABLETS.
- If your child is under the age of 18 years (see Warnings and precautions). (see Warnings and precautions).

Warning and precautions

COMPRAL® PAIN TABLETS contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose even if the person may not be showing or experiencing any symptoms, the nearest doctor, hospital or Poison Centre must be contacted immediately.
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Take special care with COMPRAL® PAIN TABLETS

- To not exceed the recommended daily dose as it may cause serious harm to your liver.
- COMPRAL® PAIN TABLETS contain paracetamol.

Do not take COMPRAL® PAIN TABLETS if you are taking any other prescription or non-prescription medicines containing paracetamol due to the possibility of paracetamol overdose.

Paracetamol overdose may cause liver failure which may require liver transplant or lead to death.

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- To not give it to children and adolescents under the age of 18 years of age.
- If your symptoms do not improve within 10 days of continuous use, please consult your doctor.
- If no relief is obtained with the recommended dosage, consult your doctor.

Excessive and prolonged use of COMPRAL® PAIN TABLETS may be dangerous.

- Seek medical advice if cough persists, or if it is accompanied by high fever, skin rash or persistent headache.
- If you suffer from liver or kidney disease, you should take COMPRAL® PAIN TABLETS under medical supervision.
- If you have existing liver disease as it increases the risk of paracetamol-related liver damage.
- If you are pregnant or plan to become pregnant, tell your doctor or health care provider.
Taking NSAIDs at around 20 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs for more than 2 days when you are between 20 and 30 weeks of your pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. You should not take NSAIDs around 30 weeks of pregnancy or later (see Do not take COMPRAL® PAIN TABLETS).
- Do not take NSAIDs such as COMPRAL® PAIN TABLETS regularly during the third trimester of pregnancy. This may result in premature closure of the foetal ductus arteriosus in utero (closure before desirable time, of the unborn baby's blood vessel which is part of the vessels connecting the lungs and heart), and possibly, in persistent pulmonary hypertension (high blood pressure in blood vessels of the lungs) of the new-born. The onset of labour may be delayed, and its duration increased (see Pregnancy, breastfeeding, and fertility).
- Avoid use of COMPRAL® PAIN TABLETS with other systemic NSAID's (non-steroidal anti-inflammatory medicines, the class to which aspirin belongs) including cyclooxygenase-2-(COX-2) selective inhibitors (e.g., piroxicam), due to the potential for additive undesirable effects. Serious hypersensitivity (allergic) reactions can occur and bronchospasm (sudden constrictions of the muscles of the passage ways by which air passes through the nose to the air sacs of the lungs) may suddenly occur in patients suffering from or with previous history of asthma, allergic disease or nasal polyps (sac like growths of inflamed tissue lining the nose or sinuses). See Other medicines and COMPRAL® PAIN TABLETS.
- if you suffer from or have a previous history of asthma, allergic disease, or nasal polyps (sac like growths of inflamed tissue lining the nose or sinuses).
- If you are scheduled to undergo any surgical procedures as the use of COMPRAL® PAIN TABLETS should be stopped several days before any scheduled surgical procedures.
- Aspirin, as in COMPRAL® PAIN TABLETS, prevents blood cells called platelets from clumping

together to form a clot, thereby increasing bleeding time. You should report any unusual bleeding symptoms to your doctor.

- If you suffer from G-6-PD deficiency (a hereditary condition leading to low red blood cell counts), you should consult your doctor, pharmacist, or healthcare professional.

Taking high doses of Aspirin, as in COMPRAL® PAIN TABLETS, more than 1g daily, may worsen acute haemolytic anaemia (increased red blood cell breakdown).

- Paracetamol, as in COMPRAL® PAIN TABLETS, can cause serious skin reactions known as severe cutaneous adverse reactions (SCARs) such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalized exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS)/Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE). You can identify these reactions by severe skin peeling, painful blisters, extremely serious allergic skin reactions accompanied by fever or flu-like symptoms, facial swelling, and painful blisters, abdominal pains, abdominal heartbeat.

If you experience any of these skin reactions, stop taking COMPRAL® PAIN TABLETS and consult your doctor immediately.

Aspirin may cause Reye's syndrome. Reye's syndrome is a rare but serious illness, in children and teenagers with chickenpox or influenza. Consult a doctor before using aspirin in such patients. For this reason, do not give COMPRAL® PAIN TABLETS to children under 18 years of age unless prescribed by a doctor. If the child changes in behaviour with nausea and vomiting, consult your doctor because these symptoms could be an early sign of Reye's syndrome.

Check with your doctor before taking COMPRAL® PAIN TABLETS if you:

- have a history of high blood pressure or heart disease, as you may experience water retention and swelling. Heart failure may suddenly occur.
- are an elderly, as you may experience an increased frequency of side effects especially having an ulcer, stomach and intestinal bleeding, which may cause death. Your risk of experiencing these side effects is higher with increasing doses of COMPRAL® PAIN TABLETS.
- have a history of ulcers, because your risk of having an ulcer, stomach and intestinal bleeding is higher, with increasing doses of COMPRAL® PAIN TABLETS.
- have a history of:
 - ulcerative colitis
 - stomach and intestinal diseases e.g. Crohn's disease (inflammatory disease of the stomach and intestine),
 - Hiatus hernia (stomach pushing up into the chest),
 - gastro-oesophageal reflux disease (digestive disorder which affects the lower gut sphincter),

- angiodysplasia (vascular malformation of the gut).

These conditions may worsen.

Check with your doctor before taking COMPRAL® PAIN TABLETS if you have:

- uncontrolled hypertension
- liver or kidney problems
- dyspepsia (a persistent or recurrent pain or discomfort in the upper abdomen)
- anaemia (deficiency of blood components that transport oxygen)
- dehydration (significantly lost body fluids)
- diabetes mellitus (a chronic disease associated with abnormally high levels of the sugar glucose in the blood).

You may need to avoid using COMPRAL® PAIN TABLETS altogether or limit the amount you take as prolonged use of high doses may lead to metabolic acidosis (a condition in which acids build up in your body), anaemia, blood disorders, stomach and intestinal bleeding, peptic ulceration and renal papillary necrosis (death of kidney papillae, that is, areas where the openings of the collecting ducts enter the kidney and where urine flows into the ureters).

Cases of liver failure have been reported in patients with depleted glutathione (a protein) levels, such as those:

- who are severely malnourished (lacking sufficient nutrients in the body)
- anorexic (lacking appetite)
- severely underweight,
- are chronic heavy users of alcohol
- have sepsis (severe infection).

In patients with glutathione (a protein) depleted states, the use of COMPRAL® PAIN TABLETS may increase the risk of metabolic acidosis. Signs of metabolic acidosis include:

- deep, rapid difficult breathing
- feeling sick (nausea), being sick (vomiting)
- loss of appetite.

Contact a doctor immediately if you get a combination of these symptoms

Excess intake of caffeine (e.g. tea, coffee and some canned drinks) should be avoided while taking COMPRAL® PAIN TABLETS.

Children and adolescents

Do not give COMPRAL® PAIN TABLETS to children under 18 years of age unless prescribed by a doctor (see Do not take COMPRAL® PAIN TABLETS and take special care with COMPRAL® PAIN TABLETS above).

Other medicines and COMPRAL® PAIN TABLETS

Always tell your healthcare provider if you are taking any other medicine (This includes complementary or traditional medicines).

The following medicines may cause an interaction when used in combination with COMPRAL® PAIN TABLETS:

- *Other NSAIDS* (Non-steroidal anti-inflammatory drugs - a class of medicines that provides pain-relieving, fever reducing and anti-inflammatory effects, e.g. ibuprofen) including acetylsalicylic acid and cyclo-oxygenase-2-(an enzyme causing inflammation also called COX-2) specific inhibitors (medicines that block COX-2). Prolonged use together with COMPRAL® PAIN TABLETS: increased risk of side effects.
- *Sulphonamides* (group of antibiotics): Possible enhanced activity of sulphonamides.
- *Sulphonylureas* (medicines used to lower blood sugar levels). e.g. glibenclamide. Aspirin, as in COMPRAL® PAIN TABLETS, may enhance the effects of anti-diabetic medicines.
- *Uricosurics* (medicine used to treat gout such as probenecid and sulphinyprazone): Aspirin, as in COMPRAL® PAIN TABLETS, can reduce the effect of uricosurics while probenecid can increase the amount of aspirin circulating in the body.
- *Barbiturates and other sedatives*: May mask the respiratory symptoms (associated with the body's breathing system) of aspirin overdose and have been reported to enhance its toxicity.
- *Other Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)*: Use of two or more NSAIDs concomitantly could result in an increase in side effects.
- *Antiepileptics* (for seizures) such as carbamazepine, phenobarbital, phenytoin or primidone: Possible decrease in desirable effects of paracetamol, as in COMPRAL® PAIN TABLETS.
- *Lamotrigine*: (mainly used to treat seizures) Paracetamol, as in COMPRAL® PAIN TABLETS, affects the metabolic disposition (fate of the medicine after it is taken into the body) of lamotrigine. The percentage of lamotrigine recovered in the urine increases and is reduced in the blood thus making it less effective.
- *Corticosteroids*: Increased risk of gastrointestinal ulceration or bleeding (PUBs).

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- *Anti-platelet medicines and selective serotonin reuptake inhibitors (SSRIs)*: Increased risk of gastrointestinal bleeding.
- *Anticoagulants and Platelet Aggregation Inhibitors* (medicines used to thin blood): Aspirin and paracetamol, as in COMPRAL® PAIN TABLETS, may enhance the effects of anticoagulants such as coumarins (e.g. warfarin) and heparin, and of platelet aggregation inhibitors such as ticlopidine, clopidogrel cilostazol as there is an increased risk of bleeding. Your doctor may monitor your bleeding time and blood-thinning therapy.
- *Thrombolytics* (used to break the clots): There is an increased risk of bleeding when taken together with COMPRAL® PAIN TABLETS. Concomitant use is therefore not recommended.
- *Loop Diuretics (medicines that result in high water loss e.g. furosemide)*: Aspirin, as in COMPRAL® PAIN TABLETS, may reduce their activity. NSAIDs can cause acute kidney failure, especially if you are dehydrated. If you take a diuretic with aspirin, it is necessary to ensure you take enough water and to have your kidney function and blood pressure monitored by the doctor, particularly when starting diuretic treatment.
- *Phenytoin*: Aspirin, as in COMPRAL® PAIN TABLETS, increases serum levels of phenytoin (amount of phenytoin present in your blood at the time of testing); serum phenytoin should be well monitored by your doctor.
- *Valproate*: Aspirin, as in COMPRAL® PAIN TABLETS, interferes with the breakdown of valproate and hence could increase valproate's toxicity; valproate levels should be well monitored by your doctor.
- *Methotrexate (≤ 15 mg/ week)*: The toxicity of methotrexate may be enhanced by use together with aspirin, as in COMPRAL® PAIN TABLETS. In case you take it together with aspirin, your doctor will monitor your kidney.
- *Alcohol*: Use together with aspirin, as in COMPRAL® PAIN TABLETS, increases the risk of stomach and intestinal bleeding.
- *Diuretics and antihypertensive agents* (medicines used to reduce water levels in your body and blood pressure e.g. *beta blockers, angiotensin converting enzyme (ACE) inhibitors*): Antihypertensive effect may be decreased. Therefore, take caution when using them together with COMPRAL® PAIN TABLETS. You should have your blood pressure periodically monitored, especially if you are an elderly. You should take adequate water and check with your doctor for consideration of monitoring kidney function after initiation of concomitant therapy and periodically thereafter, particularly for diuretics and ACE inhibitors, due to the increased risk of nephrotoxicity (damage to the kidneys).
- *Potassium-sparing medicines*: Treatment together with aspirin, as in COMPRAL® PAIN

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TABLETS, may be associated with increased serum potassium levels (amount of potassium in the blood at the time of testing). Serum potassium levels should be monitored frequently.

- *Antacids*: May increase removal of aspirin, as in COMPRAL® PAIN TABLETS, from the body by alkalisation of urine.
- *Gold compounds (medicines used in rheumatoid arthritis)*: Risk of aspirin, as in COMPRAL® PAIN TABLETS, induced liver damage may be increased.
- *Dipyridamole (medicine used to prevent clot formation)*: Aspirin, as in COMPRAL® PAIN TABLETS, side effects may be increased.
- *Metoprolol (medicine used to treat heart attacks and high blood pressure)*: Aspirin, as in COMPRAL® PAIN TABLETS, side effects may be increased.
- *Carbonic anhydrase inhibitors (medicines used to treat glaucoma e.g. acetazolamide)*: Risk of aspirin, as in COMPRAL® PAIN TABLETS, toxicity may be increased.
- *Metoclopramide* and domperidone (medicines used for nausea and vomiting): Increased absorption of paracetamol, as in COMPRAL® PAIN TABLETS.
- *Cholestyramine* (medicine used to reduce high cholesterol and to treat itching caused by partial blockage of the bile): Absorption of paracetamol, as in COMPRAL® PAIN TABLETS, is reduced if given within one hour of cholestyramine.
- *Antibacterials* such as:
 - (i) Isoniazid or Rifampicin (medicine for treatment of an infectious disease mainly of the lungs called tuberculosis) chronic use may increase the risk of liver damage when combined with paracetamol, as in COMPRAL® PAIN TABLETS, at recommended doses.
 - (ii) *Flucloxacillin* (medicine used to treat skin, wound, chest and bone infections) caution is advised when taken together with paracetamol, as in COMPRAL® PAIN TABLETS, as this may result in:
 - pyroglutamic aciduria (a condition that prevents production of glutathione, a chemical involved in important processes in the body e.g. processing medication)
 - high anion gap metabolic acidosis (condition that occurs when there is too much acid in the body, characterised by a high difference between the negatively charged and positively charged electrolytes in the blood)
- *Antivirals* such as Zidovudine (used to treat infection caused by HIV): Paracetamol, as in COMPRAL® PAIN TABLETS, may delay the metabolism of zidovudine and cause severe toxic damage to the liver.
- *Probenecid*: Pre-treatment with probenecid can decrease COMPRAL® PAIN TABLETS clearance and increase its plasma half-life.

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- *NSAIDs*: Prolonged concurrent use of COMPRAL® PAIN TABLETS with NSAIDs increases the risk of kidney problems.
- *Alcohol*: Reduces the liver's capacity to deal with paracetamol, as in COMPRAL® PAIN TABLETS.
- *Chloramphenicol*: Use of chloramphenicol with paracetamol, as in in COMPRAL® PAIN TABLETS, may enhance effect of chloramphenicol.
- *Antibacterials*: elimination half-life of caffeine, as in COMPRAL® PAIN TABLETS, increases and clearance decreases when co-administered with ciprofloxacin, enoxacin and piperidic acid. Enoxacin had the greatest inhibitory effect on the clearance.
- *Antidepressants*: Fluvoxamine has been reported to significantly enhance the effects of caffeine, as in COMPRAL® PAIN TABLETS.
- *Antiepileptics*: The effect of caffeine, as in COMPRAL® PAIN TABLETS, may be enhanced. Carbamazepine or valproic acid has no effect on caffeine, as in COMPRAL® PAIN TABLETS.
- *Methoxsalen* (used to treat psoriasis): Can reduce removal of caffeine, as in COMPRAL® PAIN TABLETS, from your body.
- *Sex hormones*: The clearance of caffeine has been reported to be reduced and its effects are enhanced in women taking oral contraceptives. This effect was also reported in postmenopausal women taking oestrogens for hormone replacement therapy.
- *Sympathomimetics*: Giving caffeine with ephedrine has been reported to produce significant cardiovascular, metabolic, and hormonal responses, including increased systolic blood pressure and heart rate, and raised fasting glucose and insulin.
- *Lithium*: Caffeine, as in COMPRAL® PAIN TABLETS, can increase the elimination of lithium from the body. This can enhance the effects of lithium. Therefore, concomitant use is not recommended.
- *Allopurinol* (medicine used to treat gout): Allopurinol has been reported to enhance the effects of caffeine, as in COMPRAL® PAIN TABLETS.
- *Cimetidine* (medicine used for heartburn, ulcers, increased acid production and other associated symptoms): Cimetidine has been reported to enhance the effects of caffeine, as in COMPRAL® PAIN TABLETS.

COMPRAL® PAIN TABLETS with food, drink and alcohol

Avoid excessive intake of caffeine (e.g. coffee, tea and some canned drinks) while taking COMPRAL® PAIN TABLETS.

If you take aspirin with alcohol, it could increase the risk of stomach and intestinal bleeding.

Pregnancy, breastfeeding, and fertility

The use of COMPRAL® PAIN TABLETS during pregnancy and breastfeeding is not recommended.

If you are pregnant, or breast-feeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking COMPRAL® PAIN TABLETS.

COMPRAL® PAIN TABLETS is not to be taken during the first and third trimesters of pregnancy, except under the advice and supervision of a medical doctor.

Regular use of NSAIDs such as COMPRAL® PAIN TABLETS 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, with increased risk of bleeding tendency in both the mother and child. If the expected benefit to the mother is greater than the possible risk to the foetus, the lowest effective dose and the shortest duration of treatment should be considered.

Caffeine, as in COMPRAL® PAIN TABLETS, is not recommended for use during pregnancy due to the possible increased risk of spontaneous abortion associated with caffeine consumption.

COMPRAL® PAIN TABLETS Not recommended for use during breastfeeding. Aspirin is secreted into breastmilk in low concentrations. There is insufficient information on the effects of aspirin at low concentration in infants. Treatment should be avoided during lactation because of the possible risk of Reye's syndrome and the potential impairment of platelet function in the infant. Paracetamol is excreted in breastmilk but not in a significant amount at recommended dosages. Caffeine in breastmilk may potentially have a stimulating effect on breast fed infants but significant toxicity has not been observed.

Driving and using machines

COMPRAL® PAIN TABLETS can cause side effects, such as dizziness and vertigo (sensation of swaying or spinning). You should not drive or operate machinery if you experience these effects.

3. How to take COMPRAL® PAIN TABLETS

Do not share medicines prescribed for you with any other person.

Always take COMPRAL® PAIN TABLETS exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

DO NOT EXCEED THE RECOMMENDED DOSE.

Not for use in children and adolescents under 18 years of age.

Use the lowest effective dose for the shortest possible duration of treatment.

Adults: 1 to 2 tablets, 4 hourly.

Not more than 4 doses in 24 hours. This means not more than 8 tablets in 24 hours.

If you take more COMPRAL® PAIN TABLETS than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Paracetamol

You will require specialised treatment as soon as possible. A delay in starting treatment may mean that antidote (medicine to counteract the overdose) is given too late to be effective. Usually, liver damage can only be confirmed after the time for effective treatment has passed.

You may be prone to paracetamol poisoning if you take repeated high doses (greater than 5 -10 g/day) of COMPRAL® PAIN TABLETS for several days, if you suffer from chronic alcoholism, chronic liver disease, AIDS, malnutrition, and if you use medicines such as barbiturates (for anxiety, insomnia and seizures), isoniazid (for tuberculosis), rifampicin (for tuberculosis), phenytoin (for seizures) and carbamazepine (for seizures).

Symptoms of paracetamol overdosage seen in the first 24 hours are:

- pale skin
- nausea
- vomiting
- loss of appetite
- abdominal pain

Mild symptoms during the first two days of acute poisoning, do not reflect the potential seriousness of the overdosage.

Other symptoms are:

- liver damage or injury 12 to 48 hours after taking COMPRAL® PAIN TABLETS but sometimes delayed.

- abnormalities of glucose breakdown
- excess quantity of acid in the blood.
- liver damage which may progress to disease of the brain, coma and death.
- Cardiac arrhythmias (irregular heartbeat)
- Inflammation of the pancreas
- Cerebral oedema (swelling of the brain) and nonspecific myocardial depression
- Acute renal failure

N-acetylcysteine should be given to all cases of suspected overdose as soon as possible, preferably within 8 hours of overdosage, although treatment up to 36 hours after overdosing may still be of benefit.

IV (via the vein): An initial dose of 150 mg/kg in 200 ml glucose injection, given intravenously (IV) over 15 minutes, followed by an 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.**

Orally (by mouth) not the treatment of choice: 140 mg/kg dissolved in water may be taken initially, followed by 70 mg/kg solution every four (4) hours for seventeen (17) doses.

Aspirin

Symptoms of aspirin overdosage include:

- dizziness
- tinnitus (ringing in the ears) or deafness
- vertigo (loss of balance)
- sweating
- nausea or vomiting
- mental confusion
- increased respiratory rate (number of breaths per minute)
- hyperventilation (fast breathing)
- warm hands and feet with rapid pulses
- increased acid in the blood,
- increase in ketones in the blood
- reduced functioning of the central nervous system.

In children serious signs of overdosage may develop rapidly.

Uncommon features include haematemesis, hyperpyrexia, hypoglycaemia, hypokalaemia, thrombocytopaenia, increased INR/ PTR, intravascular coagulation, renal failure and noncardiac, pulmonary oedema. Central nervous system features including confusion, disorientation, coma and convulsions are less common in adults than in children.

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.

Caffeine

Symptoms of caffeine overdosage include:

- epigastric pain (pain in the upper region of the abdomen)
- vomiting
- diuresis (increased urination)
- facial flushing (an involuntary reddening of the face)
- cardiac arrhythmia
- restlessness
- excitement
- agitation
- anxiety
- convulsions (seizures)
- muscle tremor
- tinnitus (ringing in the ears)
- visual spot disturbances
- increased rate or rhythm of heartbeat
- abnormal heartbeats.

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.

If you forget to take a dose of COMPRAL® PAIN TABLETS

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

COMPRAL® PAIN TABLETS can have side effects.

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Not all side effects reported for COMPRAL® PAIN TABLETS are included in this leaflet. Should your general health worsen or if you experience untoward effects while taking COMPRAL® PAIN TABLETS, please consult your healthcare care provider for advice.

If any of the following happen, stop taking COMPRAL® PAIN TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Fever, skin rash, swelling of the lymph nodes and/or swelling of the face (also known as DRESS). The rash may be red or itchy with swelling but sometimes may be more serious and accompanied by fever and ulcers or abscesses.
- Blisters on your skin or inside your mouth, nose, vagina, or bottom.
- The appearance of a rash or sunburn when you have been outside (even on a cloudy day).
- Other allergic reactions such as itching, or wheezing, coughing or difficulty breathing, or swelling of the lips and tongue.
- You experienced any bleeding from your stomach (symptoms can include blood in your stools or vomit).
- You experienced an increase in the number of nosebleeds or bruising.
- You experienced ringing in your ears or temporary hearing loss.
- You experienced any water retention.
- When used in children, changes in behaviour, nausea and vomiting occur (it could be early signs of Reye's syndrome).
- Serious skin reactions such as swelling, itching, red severe rash especially those covering your whole body (appearing as allergic wheals), (see section 2).

These are very serious side effects. If you have them, you may have had a serious reaction to COMPRAL® PAIN TABLETS. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less Frequent

Paracetamol

- Blood related reactions including low blood platelet count, lack of white blood cells, and a type of anaemia in which the red blood cells, white blood cells and platelets are all reduced in number.
- Skin rashes and other allergic reactions such as itching, or wheezing, coughing or difficulty breathing, or swelling of the lips, tongue and face. The rash may be red or itchy with swelling but sometimes may be more serious and accompanied by fever and ulcers or abscesses.
- Pyroglutamic aciduria (an inherited disorder of amino acid metabolism)

- Hearing loss
- Liver problems (yellow eyes and skin, nausea, stomach pain).

Frequency unknown:

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- Drug-induced hypersensitivity syndrome (severe reaction usually characterized by fever, rash, and multiorgan failure)
- Kidney problems
- High blood pressure
- Pancreatitis
- Fixed drug eruptions (these are dermatological manifestations of medicine reactions that often occur in the same location upon re-exposure to a medicine).

Aspirin

- Blood and lymphatic system disorders: Prolonged bleeding time, anaemia
- Immune system disorders: Hypersensitivity reactions
- Metabolism and nutrition disorders: Sodium retention and fluid retention.
- Ear and labyrinth disorders: Temporary hearing loss
- Nervous system disorders: Dizziness, aseptic meningitis (inflammation of the tissues surrounding the brain and spinal cord), and headache
- Cardiovascular: Swelling, high blood pressure, heart failure
- Respiratory, thoracic, and mediastinal disorders: Difficulty in breathing or wheezing, worsening of asthma.
- Gastrointestinal: Ulcers in stomach or duodenum, gastrointestinal bleeding, which can sometimes cause death. Nausea, vomiting, diarrhoea, flatulence, constipation, indigestion, abdominal pain, faeces containing digested blood, vomiting blood, mouth ulcers and cold sores, worsening of inflammation of the colon and inflammatory disease which affects the stomach and intestinal tract, inflammation of the stomach.
- Skin reactions: Raised bumps which contain fluid, including Stevens-Johnson syndrome (rare skin disorder) and severe skin reaction.
- Kidney and Urinary Disorders: Kidney problems, increased uric acid in urine. Prolonged use of high doses may lead to renal papillary necrosis.

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- Gastrointestinal disorders: Nausea, increased stomach secretions and stomach ulcers.
- Cardiac disorders: Palpitation, tachycardia (abnormally fast heartbeat).
- Psychiatric disorders: Difficulty sleeping, restlessness, anxiety, irritability and nervousness.
- Nervous system disorders: Dizziness, headache, convulsions (uncontrollable shaking that is rapid and rhythmic, with the muscles contracting and relaxing repeatedly), excitement, loss of one or more types of sensory perception and muscle tremor (involuntary movements).
- Vertigo (sensation of spinning or swaying).
- Tinnitus (ringing in the ears)
- Increased urination.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist, or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**” found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of COMPRAL® PAIN TABLETS.

You may also report to Adcock Ingram Limited using the following e-mail address:

Adcock.AEReports@adcock.com.

5. How to Store COMPRAL® PAIN TABLETS

Store all medicines out of reach of children.

Store at or below 25 °C in a well closed container. Exposure to air should be kept to a minimum.

Do not store in a bathroom.

Do not use after the expiry date stated on the polypaper, blister or tracer pack or carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What COMPRAL® PAIN TABLETS contains

The active substances are:

Paracetamol	100,00 mg
Aspirin	400,00 mg
Caffeine anhydrous	30,00 mg

The other ingredients are:

Acacia

Starch corn

Purified talc

Hydrogenated cotton seed oil

Sodium lauryl sulphate

Colloidal silicon dioxide

Microcrystalline cellulose

What COMPRAL® PAIN TABLETS looks like and contents of the pack

COMPRAL® PAIN TABLETS are white, scored, bevel-edged tablets with the word “COMPRAL” imprinted on one side. Each pack comes in the either of the forms below:

- Polypaper strips of 2 tablets packed in a display carton or a display board of 48 x 2's,
- ALU/PVC/PVDC blister packs containing 12, 24, 36 or 72 tablets,
- ALU/ALU blister packs of 2 tablets, packed into a display carton of 50 x 2's
- ALU/ALU blister packs of 6 tablets per strip packed into cardboard cartons of 12, 24, 48 and 96 tablets,
- PP/HDPE tracer packs of 50 and 100 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Customer Care: 0860 ADCOCK / 232625

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Access to the corresponding professional information

The PI will be included in the medicine package

PATIENT INFORMATION LEAFLET

Namibia: NS0 - 04/2.8/1021

Botswana: S4 - B9311140