SCHEDULING STATUS

S0 – Pack sizes of 38 or smaller

COMPRAL®PAIN POWDERS

Aspirin 453,6 mg, Caffeine 64,8mg and Paracetamol 324mg powders

Sugar free

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

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

- Keep this leaflet. You may need to read it again.
- Do not share COMPRAL® PAIN POWDERS 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 POWDERS is and what it is used for
2. What you need to know before you take COMPRAL® PAIN POWDERS
3. How to take COMPRAL® PAIN POWDERS
4. Possible side effects
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1. What COMPRAL® PAIN POWDERS is and what it is used for

COMPRAL® PAIN POWDERS belongs to a group of medicines called analgesic combinations. COMPRAL® PAIN POWDERS is used 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, pain associated with colds or flu and fever.

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

Do not take COMPRAL® PAIN POWDERS:

- If you have or ever had a problem of your blood not clotting properly, have 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 POWDERS (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 NSAIDs. (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 NSAID's (class of medicines which aspirin belongs to) including COMPRAL® PAIN POWDERS.
- If you have kidney failure, liver failure 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 your child is under the age of 18 years (see Warnings and precautions).

Warning and precautions

COMPRAL® PAIN POWDERS 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.

Take special care with COMPRAL® PAIN POWDERS:

- To not exceed the recommended daily dose as it may cause serious harm to your liver.
- COMPRAL® PAIN POWDERS contain paracetamol.
  Do not take COMPRAL® PAIN POWDERS if you are taking any other prescription or nonprescription 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.
- 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 POWDERS 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 POWDERS 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 POWDERS).
- Do not take NSAIDs such as COMPRAL® PAIN POWDERS 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 newborn. The onset of labour may be delayed, and its duration increased (see Pregnancy, breastfeeding, and fertility).
- Avoid use of COMPRAL® PAIN POWDERS 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 POWDERS.
- 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 POWDERS should be stopped several days before any scheduled surgical procedures.
- Aspirin, as in COMPRAL® PAIN POWDERS, 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 POWDERS, more than 1 g daily, may worsen acute haemolytic anaemia (increased red blood cell breakdown).
- Paracetamol, as in COMPRAL® PAIN POWDERS, 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 POWDERS 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 POWDERS 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 POWDERS 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 POWDERS.
- have a history of ulcers, because your risk of having an ulcer, stomach and intestinal bleeding is higher, with increasing doses of COMPRAL® PAIN POWDERS.
- 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 POWDERS if you have:

- uncontrolled hypertension
- liver or kidney problems
- heart 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 POWDERS 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 POWDERS 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.

Avoid excess intake of caffeine (e.g. tea, coffee and some canned drinks) while taking COMPRAL® PAIN POWDERS as it contains caffeine.

Children and adolescents

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

Other medicines and COMPRAL® PAIN POWDERS

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 POWDERS:

- *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 POWDERS: 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 POWDERS, may enhance the effects of anti-diabetic medicines.
- *Uricosurics* (medicine used to treat gout such as probenecid and sulphinpyrazone): Aspirin, as in COMPRAL® PAIN POWDERS, 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 overdosage 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 POWDERS.
- *Lamotrigine:* (mainly used to treat seizures) Paracetamol, as in COMPRAL® PAIN POWDERS, 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).
- *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 POWDERS, 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 POWDERS. Concomitant use is therefore not recommended.

- *Loop Diuretics (medicines that result in high water loss e.g. furosemide)*: Aspirin, as in COMPRAL® PAIN POWDERS, 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 POWDERS, 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 POWDERS, 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 POWDERS. In case you take it together with aspirin, your doctor will monitor your kidney.
- *Alcohol:* Use together with aspirin, as in COMPRAL® PAIN POWDERS, 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 POWDERS. 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 POWDERS, 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 POWDERS, from the body by alkalinisation of urine.
- *Gold compounds (medicines used in rheumatoid arthritis):* Risk of aspirin, as in COMPRAL® PAIN POWDERS, induced liver damage may be increased.

- *Dipyridamole (medicine used to prevent clot formation):* Aspirin, as in COMPRAL® PAIN POWDERS, side effects may be increased.
- *Metoprolol (medicine used to treat heart attacks and high blood pressure):* Aspirin, as in COMPRAL® PAIN POWDERS, side effects may be increased.
- *Carbonic anhydrase inhibitors (medicines used to treat glaucoma e.g. acetazolamide):* Risk of aspirin, as in COMPRAL® PAIN POWDERS, toxicity may be increased.
- *Metoclopramide* and domperidone (medicines used for nausea and vomiting): Increased absorption of paracetamol, as in COMPRAL® PAIN POWDERS.
- *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 POWDERS, 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 POWDERS, 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 POWDERS, 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 POWDERS, may delay the metabolism of zidovudine and cause severe toxic damage to the liver.
- *Probenecid*: Pre-treatment with probenecid can decrease COMPRAL® PAIN POWDERS clearance and increase its plasma half-life.
- *NSAIDS*: Prolonged concurrent use of COMPRAL® PAIN POWDERS with NSAIDS increases the risk of kidney problems.
- *Alcohol:* Reduces the liver's capacity to deal with paracetamol, as in COMPRAL® PAIN POWDERS.

- *Chloramphenicol:* Use of chloramphenicol with paracetamol, as in in COMPRAL® PAIN POWDERS, may enhance effect of chloramphenicol.
- *Antibacterials*: elimination half-life of caffeine, as in COMPRAL® PAIN POWDERS, increases and clearance decreases when co-administered with ciprofloxacin, enoxacin and pipemidic 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 POWDERS.
- *Antiepileptics*: The effect of caffeine, as in COMPRAL® PAIN POWDERS, may be enhanced. Carbamazepine or valproic acid has no effect on caffeine, as in COMPRAL® PAIN POWDERS.
- *Methoxsalen* (used to treat psoriasis): Can reduce removal of caffeine, as in COMPRAL® PAIN POWDERS, 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 POWDERS, 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 POWDERS.
- *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 POWDERS.

COMPRAL® PAIN POWDERS with food, drink and alcohol

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

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 POWDERS during pregnancy and breastfeeding is not recommended.

If you are pregnant, or breastfeeding, 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 POWDERS.

COMPRAL® PAIN POWDERS 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 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 newborn.

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 POWDERS, is not recommended for use during pregnancy due to the possible increased risk of spontaneous abortion associated with caffeine consumption.

COMPRAL® PAIN POWDERS is 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 POWDERS 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 POWDERS

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

Always take COMPRAL® PAIN POWDERS 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: 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.

If you take more COMPRAL® PAIN POWDERS 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 POWDERS 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 POWDERS 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 dysrhythmias (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, especially if more than 150 mg/kg of paracetamol was taken.
IV (via the vein): An initial dose of 150 mg/kg N-acetylcysteine in 200 ml dextrose injection, given intravenously (IV) over 15 minutes, followed by an 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 (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 vomiting of blood, high body temperature, low blood sugar, low potassium blood level, low platelet blood count, delayed blood clotting, blood flow disruption, kidney failure and non-heart related excess of fluid in the lungs. Central nervous system features including confusion, disorientation, coma and involuntary contraction of muscles 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 dysrhythmia
- 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 POWDERS

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

4. Possible side effects

COMPRAL® PAIN POWDERS can have side effects.

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

If any of the following happen, stop taking COMPRAL® PAIN POWDERS 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 (Warning and precautions, *Take special care with COMPRAL® PAIN POWDERS*).

These are very serious side effects. If you have them, you may have had a serious reaction to COMPRAL® PAIN POWDERS. 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.
- Pyroglutamic aciduria (an inherited disorder of amino acid metabolism)
- Hearing loss
- 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.
- Liver problems (yellow eyes and skin, nausea, stomach pain).

Frequency unknown:

Paracetamol

- Drug-induced hypersensitivity syndrome (severe reaction usually characterized by fever, rash, and multiorgan failure).
- Kidney problems
- High blood pressure
- Inflammation of the pancreas
- 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, blood dyscrasis, thrombocytopenia
- Immune system disorders: Hypersensitivity reactions
- Metabolism and nutrition disorders: Sodium retention and fluid retention

- Ear and labyrinth disorders: Temporary hearing loss, tinnitus
- 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.
- Hepatobiliary: Raised liver enzymes, Reye's syndrome (in children and adolescents under the age of 18 years of age), which can be fatal that causes brain and liver damage. Usually occurs in children who have had a recent viral infection, such as chickenpox or the flu.
- 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 (a type of damage that occurs in your kidneys).

Caffeine

- Gastrointestinal disorders: Nausea, increased stomach secretions and stomach ulcers.
- Cardiac disorders: Palpitations, 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 POWDERS. You may also report to Adcock Ingram Limited using the following e-mail address: Adcock.AEReports@adcock.com.

5. How to Store COMPRAL® PAIN POWDERS

Store all medicines out of reach of children.
Store in airtight containers, protected from light at or below 25 °C.
Do not store in a bathroom.
Do not use after the expiry date stated on the polypaper 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 POWDERS contains The active substances are:

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

The other ingredient

Colloidal Anhydrous Silica

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

COMPRAL® PAIN POWDERS is a fine, white, crystalline powder with a slight acidic odour
846 mg of powder is packed in polypaper sachets in packs of 2, 10, 24, 38, and in single doses.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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SKEDULERINGSTATUS

S0 – Verpakkingsgroottes van 38 of kleiner

COMPRAL® PAIN POWDERS

Aspirien 453,6 mg, Kafeïen 64,8mg en Parasetamol 324mg poeiers

Suikervry

Lees hierdie hele biljet noukeurig deur, want dit bevat belangrike inligting vir u COMPRAL® PAIN POWDERS is beskikbaar sonder 'n doktersvoorskrif, vir u om 'n minder ernstige siekte te behandel. Nietemin moet u steeds COMPRAL® PAIN POWDERS versigtig gebruik om die beste resultate daaruit te verkry.

- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Moenie COMPRAL® PAIN POWDERS met enige ander persoon deel nie.
- Vra u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.
- U moet 'n dokter raadpleeg indien u simptome vererger, of nie na 10 dae verbeter nie.

Wat in hierdie biljet is

1. Wat COMPRAL® PAIN POWDERS is en waarvoor dit gebruik word
2. Wat u moet weet voordat u COMPRAL® PAIN POWDERS neem
3. Hoe om COMPRAL® PAIN POWDERS te neem
4. Moontlike newe-effekte
5. Hoe om COMPRAL® PAIN POWDERS te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat COMPRAL® PAIN POWDERS is en waarvoor dit gebruik word

COMPRAL® PAIN POWDERS behoort tot 'n groep medisyne wat analgetiese kombinasies genoem word. COMPRAL® PAIN POWDERS word gebruik vir die simptomatiese verligting van ligte tot matige pyn soos hoofpyn, dismenoree (pynlike menstruasie), pyn in spiere en gewrigte, tandpyn en inflammasie, pyn wat verband hou met verkoue of griep en koors.

2. Wat u moet weet voordat u COMPRAL® PAIN POWDERS neem

Moenie COMPRAL® PAIN POWDERS neem nie:

- Indien u 'n probleem het, of ooit gehad het, dat u bloed nie behoorlik stol nie, lewerfunksieprobleme het of indien u medisyne neem om bloedstolling te verminder.
- Indien u hipersensitief (allergies) is vir aspirien of ander NSAIM's, parasetamol, kafeïen of vir enige van die ander bestanddele van COMPRAL® PAIN POWDERS (gelys in afdeling 6).
- Indien u 'n geskiedenis van asma, bronchospasma het (skielike sametrekkings van die spiere van die gangweë waardeur lug deur die neus na die lugsakke van die longe beweeg), angio-edeem (pynlose swelling van die weefsellaag onder die vel), rinitis (irritasie en inflammasie van die slymvliese in die neus), urtikaria (galbulte), wanneer u aspirien of NSAIM's neem. (NSAIM's - klas medisyne waaraan aspirien behoort).
- Indien u 'n maagseer gehad het, of ooit gehad het, skade of bloeding van die maag wat verband hou met vorige gebruik van aspirien en ander NSAIM's (klas medisyne waaraan aspirien behoort), insluitend COMPRAL® PAIN POWDERS.
- Indien u nierversaking, lewerversaking of hartversaking het.
- Indien u jig het, of ooit gehad het.
- Indien u swanger is, moenie NSAIM's op 30 weke of later in u swangerskap gebruik nie, want hierdie medisyne kan probleme by u ongebore baba veroorsaak.
- Indien u kind jonger as 18 jaar is (sien Waarskuwings en voorsorgmaatreëls).

Waarskuwing en voorsorgmaatreëls

COMPRAL® PAIN POWDERS bevat parasetamol wat dodelik kan wees in oordosis. In die geval van oordosering of vermoedelike oordosis, selfs al toon of ervaar die persoon geen simptome nie, moet die naaste dokter, hospitaal of gifhulpsentrum onmiddellik gekontak word.

Wees veral versigtig met COMPRAL® PAIN POWDERS:

- Om nie die aanbevole daaglikse dosis te oorskry nie, aangesien dit ernstige skade aan u lewer kan veroorsaak.
- COMPRAL® PAIN POWDERS bevat parasetamol.
  Moenie COMPRAL® PAIN POWDERS neem indien u enige ander voorskrif of nie-voorskrifmedisyne neem wat parasetamol bevat nie as gevolg van die moontlikheid van parasetamol-oordosis.

Parasetamol-oordosis kan lewerversaking veroorsaak wat leweroorplanting kan vereis of tot die dood kan lei.

- Om dit nie aan kinders en adolessente onder die ouderdom van 18 jaar te gee nie.
- Indien u simptome nie binne 10 dae van ononderbroke gebruik verbeter nie, raadpleeg asseblief u dokter.
- Indien geen verligting verkry word met die aanbevole dosis nie, raadpleeg u dokter. Oormatige en langdurige gebruik van COMPRAL® PAIN POWDERS kan gevaarlik wees.
- Soek mediese advies indien hoes voortduur, of indien dit gepaard gaan met hoë koors, veluitslag of aanhoudende hoofpyn.
- Indien u aan lewer- of niersiekte ly, moet u COMPRAL® PAIN POWDERS onder mediese toesig neem.
- Indien u bestaande lewersiekte het, verhoog dit die risiko van parasetamol-verwante lewerskade.
- Indien u swanger is of van plan is om swanger te raak, lig u dokter of gesondheidsorgverskaffer in. Indien u NSAIM's teen ongeveer 20 weke van swangerskap of later neem, kan dit u ongebore baba benadeel. Indien u NSAIM's vir langer as 2 dae moet neem tussen 20 en 30 weke van u swangerskap, moet u gesondheidsorgverskaffer dalk die hoeveelheid vloeistof in u baarmoeder rondom u baba monitor. U moet nie NSAIM's teen ongeveer 30 weke van swangerskap of later neem nie (sien Moenie COMPRAL® PAIN POWDERS neem nie).
- Moenie NSAIM's soos COMPRAL® PAIN POWDERS gereeld gedurende die derde trimester van swangerskap neem nie. Dit kan lei tot voortydige sluiting van die fetale *ductus arteriosus in utero* (sluiting van die ongebore baba se bloedvat, wat deel is van die vate wat die longe en hart verbind, voor die gewenste tyd), en moontlik tot aanhoudende pulmonale hipertensie (hoë bloeddruk in bloedvate van die longe) van die pasgeborene. Die aanvang van kraam kan vertraag word, en die duur daarvan kan verleng word (sien Swangerskap, borsvoeding en vrugbaarheid).
- Vermy die gebruik van COMPRAL® PAIN POWDERS met ander sistemiese NSAIM's (nie-steroïed anti-inflammatoriese medisyne, die klas waaraan aspirien behoort), insluitend siklo-oksigenase-2 (COX-2) selektiewe inhibeerders (bv. piroksikaam), as gevolg van die potensiaal vir verhoogde ongewenste effekte. Ernstige hipersensitiwiteit (allergiese) reaksies kan voorkom en bronchospasma (skielike sametrekkings van die spiere van die gangweë waardeur lug deur die neus na die lugsakke van die longe beweeg) kan skielik voorkom by

pasiënte wat ly aan, of met 'n vorige geskiedenis van asma, allergiese siektes of neuspoliepe (sak-agtige groeisels van ontsteekte weefsel wat die neus of sinusse uitvoer). Sien Ander medisyne en COMPRAL® PAIN POWDERS.

- Indien u ly aan, of 'n vorige geskiedenis van asma, allergiese siektes of neuspoliepe het (sak-agtige groeisels van ontsteekte weefsel wat die neus of sinusse uitvoer).
- Indien u geskeduleer is om enige chirurgiese prosedures te ondergaan, aangesien die gebruik van COMPRAL® PAIN POWDERS 'n paar dae voor enige geskeduleerde chirurgiese prosedures gestaak moet word.
- Aspirien, soos in COMPRAL® PAIN POWDERS, verhoed dat bloedselle, wat bloedplaatjies genoem word, saambondel om 'n klont te vorm, waardeur die bloedingstyd verhoog word. U moet enige ongewone bloeding-simptome by u dokter aanmeld.
- Indien u ly aan G-6-PD-tekort ('n oorerflike toestand wat lei tot lae rooibloedseltellings), moet u dokter, apteker of gesondheidsorg kundige geraadpleeg word. Die neem van hoë dosisse Aspirien, soos in COMPRAL® PAIN POWDERS, meer as 1 g daagliks, kan akute hemolitiese anemie (verhoogde rooibloedsel-afbraak) vererger.
- Parasetamol, soos in COMPRAL® PAIN POWDERS, kan ernstige velreaksies veroorsaak wat bekend staan as ernstige kutaneuse ongewenste reaksies (SCAR's) soos toksiese epidermale nekrolise (TEN), Stevens-Johnson-sindroom (SJS), akute algemene eksantematiese pustulose (AGEP), geneesmiddelreaksie met eosinofilie en sistemiese simptome (GRESS) / Geneesmiddel-geïnduseerde hipersensitiwiteitsindroom (GIHS) en area-spesifieke geneesmiddel-uitslag (FDE). U kan hierdie reaksies identifiseer deur erge velafskilfering, pynlike blase, uiters ernstige allergiese velreaksies wat gepaard gaan met koors of griepagtige simptome, swelling in die gesig en pynlike blase, buikpyne, abdominale hartklop.

Indien u enige van hierdie velreaksies ervaar, staak die gebruik van COMPRAL® PAIN POWDERS en raadpleeg u dokter onmiddellik.

Aspirien kan Reye se sindroom veroorsaak. Reye se sindroom is 'n seldsame maar ernstige siekte by kinders en tieners met waterpokkies of griep. Raadpleeg 'n dokter voordat u aspirien by sulke pasiënte gebruik. Om hierdie rede, moenie COMPRAL® PAIN POWDERS aan kinders jonger as 18 jaar gee nie, tensy dit deur 'n dokter voorgeskryf

word. Indien die kind in gedrag verander met naarheid en braking, raadpleeg u dokter, want hierdie simptome kan vroeë tekens van Reye se sindroom wees.

Raadpleeg u dokter voordat u COMPRAL® PAIN POWDERS neem indien u:

- het 'n geskiedenis van hoë bloeddruk of hartsiektes, aangesien u waterretensie en swelling kan ervaar. Hartversaking kan skielik voorkom.
- bejaard is, aangesien u 'n verhoogde frekwensie van newe-effekte kan ervaar, veral om 'n maagseer, maag- en dermbloeding te kry, wat die dood kan veroorsaak. U risiko om hierdie newe-effekte te ervaar is hoër met toenemende dosisse COMPRAL® PAIN POWDERS.
- 'n geskiedenis het van maagsere, want u risiko om 'n maagseer, maag- en dermbloeding te kry is hoër, met toenemende dosisse COMPRAL® PAIN POWDERS.
- 'n geskiedenis het van:
  - ulseratiewe kolitis,
  - maag- en dermsiektes, bv. Crohn se siekte (inflammatoriese siekte van die maag en ingewande),
  - hiatus breuk (maag wat binne-in die bors opstoot),
  - gastro-esofageale refluksiekte (spysverteringsversteuring wat die onderste dermsfinkter aantas),
  - angio-displasie (vaskulêre misvorming van die ingewande).

Hierdie toestande kan vererger.

Raadpleeg u dokter voordat u COMPRAL® PAIN POWDERS neem indien u ly aan:

- onbeheerde hipertensie
- lewer- of nierprobleme
- hartprobleme
- dispepsie ('n aanhoudende of herhalende pyn of ongemak in die boonste buik)
- bloedarmoede (tekort aan bloedkomponente wat suurstof vervoer)
- dehidrasie (verlies van aansienlike hoeveelheid liggaamsvloeistowwe)
- diabetes mellitus ('n chroniese siekte wat verband hou met abnormaal hoë vlakke van die suikerglukose in die bloed).

U moet moontlik die gebruik van COMPRAL® PAIN POWDERS heeltemal vermy of die hoeveelheid wat u neem beperk, aangesien langdurige gebruik van hoë dosisse kan lei tot metaboliese asidose ('n toestand waarin sure in u liggaam opbou), bloedarmoede, bloedafwykings, maag- en dermbloeding, maagsere en nierpapillêre nekrose (dood van nierpapille, dit wil sê, areas waar die openinge van die versamelkanale die nier binnedring en urien in die ureters invloei).

Gevalle van lewerversaking is aangemeld by pasiënte met uitgeputte glutatioon-vlakke ('n proteïen), soos dié:

- wat ernstig ondervoed is (gebrek aan voldoende voedingstowwe in die liggaam)
- anoreksies is (gebrek aan eetlus)
- erg ondergewig is,
- chroniese hewige gebruikers van alkohol is
- sepsis het (ernstige infeksie)

By pasiënte met glutatioon-uitgeputte toestande ('n proteïen), kan die gebruik van COMPRAL® PAIN POWDERS die risiko van metaboliese asidose verhoog. Tekens van metaboliese asidose sluit in:

- diep, vinnige moeilike asemhaling
- naar voel (naarheid), naar word (braking)
- verlies aan eetlus

Kontak onmiddellik 'n dokter indien u 'n kombinasie van hierdie simptome kry.

Vermy oormatige inname van kafeïen (bv. tee, koffie en sommige geblikte drankies) terwyl u COMPRAL® PAIN POWDERS neem, aangesien dit kafeïen bevat.

Kinders en adolessente

Moenie COMPRAL® PAIN POWDERS aan kinders jonger as 18 jaar gee nie, tensy dit deur 'n dokter voorgeskryf word (sien Moenie COMPRAL® PAIN POWDERS neem nie en Wees veral versigtig met COMPRAL® PAIN POWDERS hierbo).

Ander medisyne en COMPRAL® PAIN POWDERS

Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem (Dit sluit komplementêre of tradisionele medisyne in).

Die volgende medisyne kan 'n interaksie veroorsaak wanneer dit in kombinasie met COMPRAL® PAIN POWDERS gebruik word:

- *Ander NSAIM's* (nie-steroïed anti-inflammatoriese middels - 'n klas medisyne wat pynstillende, koorsverlagende en anti-inflammatoriese effekte bied, bv. ibuprofeen) insluitende asetielsalisielsuur en siklo-oksigenase-2-spesifieke (COX-2) ('n ensiem wat inflammasie veroorsaak) inhibeerders. Langdurige gebruik daarvan saam met COMPRAL® PAIN POWDERS: verhoogde risiko van newe-effekte.
- *Sulfonamiede* (groep antibiotika): Moontlike verhoogde aktiwiteit van sulfonamiede.
- *Sulfonielureas* (medisyne wat gebruik word om bloedsuikervlakke te verlaag). bv. glibenklamied. Aspirien, soos in COMPRAL® PAIN POWDERS, kan die effekte van anti-diabetiese medisyne verhoog.
- *Urikosuriese middels* (medisyne wat gebruik word om jig te behandel soos probenesied en sulfinpirasoon): Aspirien, soos in COMPRAL® PAIN POWDERS, kan die effek van urikosuriese middels verlaag, terwyl probenesied die hoeveelheid aspirien wat in die liggaam sirkuleer, kan verhoog.
- *Barbiturate en ander kalmeermiddels*: Kan die respiratoriese simptome (wat verband hou met die liggaam se asemhalingstelsel) van aspirien-oordosis maskeer en daar is aangemeld dat dit die toksisiteit daarvan verhoog.
- *Ander nie-steroïed anti-inflammatoriese middels (NSAIM's):* Die gebruik van twee of meer NSAIM's gelyktydig kan lei tot 'n toename in newe-effekte.
- *Anti-epileptiese middels* (vir stuipaanvalle) soos karbamasepien, fenobarbitaal, fenitoïen of primidoon: Moontlike afname in gewenste effekte van parasetamol, soos in COMPRAL® PAIN POWDERS.
- *Lamotrigien:* (hoofsaaklik gebruik om stuipaanvalle te behandel) Parasetamol, soos in COMPRAL® PAIN POWDERS, beïnvloed die metaboliese ingesteldheid (afbraak van die medisyne nadat dit in die liggaam ingeneem is) van lamotrigien. Die persentasie lamotrigien wat in die urien herwin word neem toe, en word laer in die bloed, wat dit minder effektief maak.

- *Kortikosteroïede*: Verhoogde risiko van gastro-intestinale ulserasie of bloeding (PUB's).
- *Anti-bloedplaatjie medisyne en selektiewe serotonienheropname inhibeerders (SSHI's):* Verhoogde risiko van gastro-intestinale bloeding.
- *Antikoagulante en bloedplaatjie-aggregasie inhibeerders* (medisyne wat gebruik word om bloed te verdun): Aspirien en parasetamol, soos in COMPRAL® PAIN POWDERS, kan die effekte van antikoagulante soos kumariene (bv. warfarien) en heparien versterk, en van bloedplaatjie-aggregasie inhibeerders soos tiklopidien, klopidogrel silostazol, aangesien daar 'n verhoogde risiko van bloeding is. U dokter kan u bloedingstyd en bloedverdunnende terapie monitor.
- *Trombolitiese middels* (gebruik om die klonte op te breek): Daar is 'n verhoogde risiko van bloeding wanneer dit saam met COMPRAL® PAIN POWDERS geneem word. Gelyktydige gebruik word dus nie aanbeveel nie.
- *Buigingsdiuretika (medisyne wat hoë waterverlies tot gevolg het, bv. furosemied):* Aspirien, soos in COMPRAL® PAIN POWDERS, mag hul aktiwiteit verlaag. NSAIM’s kan akute nierversaking veroorsaak, veral indien u gedehidreer is. Indien u 'n diuretikum met aspirien neem, is dit nodig om te verseker dat u genoeg water inneem en om u nierfunksie en bloeddruk deur die dokter te laat monitor, veral wanneer diuretiese behandeling begin word.
- *Fenitoïen:* Aspirien, soos in COMPRAL® PAIN POWDERS, verhoog serumvlakke van fenitoïen (hoeveelheid fenitoïen teenwoordig in u bloed ten tyde van toetsing); serum fenitoïen moet goed deur u dokter gemonitor word.
- *Valproaat:* Aspirien, soos in COMPRAL® PAIN POWDERS, meng in met die afbraak van valproaat en kan dus valproaat se toksisiteit verhoog; valproaatvlakke moet goed deur u dokter gemonitor word.
- *Metotreksaat (≤15 mg / week):* Die toksisiteit van metotreksaat kan verhoog word deur die gebruik daarvan saam met aspirien, soos in COMPRAL® PAIN POWDERS. Indien u dit saam met aspirien neem, sal u dokter u niere monitor.
- *Alkohol:* Gebruik saam met aspirien, soos in COMPRAL® PAIN POWDERS, verhoog die risiko van maag- en dermbloeding.
- *Diuretika en antihipertensiewe middels* (medisyne wat gebruik word om watervlakke in u liggaam en bloeddruk te verlaag *, bv. beta-blokkers, angiotensien omskakelingsensiem (AOE) inhibeerders):* Antihipertensiewe effek mag verlaag word. Wees dus versigtig wanneer u dit saam met COMPRAL® PAIN POWDERS gebruik. U moet u bloeddruk periodiek laat monitor,

veral indien u 'n bejaarde is. U moet voldoende water neem en met u dokter nagaan vir oorweging van die monitering van nierfunksie na die aanvang van gepaardgaande terapie en gereeld daarna, veral vir diuretika en AOE-inhibeerders, as gevolg van die verhoogde risiko van nefrotoksisiteit (skade aan die niere).

- *Kaliumsparende medisyne*: Behandeling saam met aspirien, soos in COMPRAL® PAIN POWDERS, kan geassosieer word met verhoogde serumkaliumvlakke (hoeveelheid kalium in die bloed ten tyde van toetsing). Serumkaliumvlakke moet gereeld gemonitor word.
- *Teensuurmiddels*: Kan die uitskeiding van aspirien, soos in COMPRAL® PAIN POWDERS, uit die liggaam verhoog deur alkalinisering van urien.
- *Goud-verbindings (medisyne wat in rumatoïede artritis gebruik word):* Risiko van aspirien, soos in COMPRAL® PAIN POWDERS, kan geïnduseerde lewerskade verhoog word.
- *Dipiridamool (medisyne wat gebruik word om klontvorming te voorkom):* Aspirien, soos in COMPRAL® PAIN POWDERS, kan newe-effekte verhoog.
- *Metoprolol (medisyne wat gebruik word om hartaanvalle en hoë bloeddruk te behandel):* Aspirien, soos in COMPRAL® PAIN POWDERS, kan newe-effekte verhoog.
- *Koolsuuranhidrase-remmers (medisyne wat gebruik word om gloukoom te behandel, bv. asetasoolamied):* Risiko dat aspirien, soos in COMPRAL® PAIN POWDERS, toksisiteit kan verhoog.
- *Metoklopramied en domperidoon (medisyne wat gebruik word vir naarheid en braking):* Verhoogde absorpsie van parasetamol, soos in COMPRAL® PAIN POWDERS.
- *Cholestiramien (medisyne wat gebruik word om hoë cholesterol te verminder en om jeukerigheid te behandel wat veroorsaak word deur gedeeltelike verstopping van die gal):* Absorpsie van parasetamol, soos in COMPRAL® PAIN POWDERS, word verminder as dit binne een uur na cholestiramien gegee word.
- *Antibakteriese middels* soos:

  (i) *Isoniasied of Rifampisien (medisyne vir die behandeling van 'n aansteeklike siekte hoofsaaklik van die longe wat tuberkulose genoem word):* Chroniese gebruik kan die risiko van lewerskade verhoog wanneer dit gekombineer word met parasetamol, soos in COMPRAL® PAIN POWDERS, teen aanbevole dosisse.

  (ii) *Flukloksasillien (medisyne wat gebruik word om vel-, wond-, bors- en beeninfeksies te behandel):* Wees versigtig wanneer dit saam met parasetamol geneem word, soos in COMPRAL® PAIN POWDERS, aangesien dit kan lei tot:

-piroglutamien suur-urien ('n toestand wat die produksie van glutatioon verhoed, 'n chemikalie wat betrokke is by belangrike prosesse in die liggaam, bv. die verwerking van medikasie)
- hoë anioongaping metaboliese asidose (toestand wat voorkom wanneer daar te veel suur in die liggaam is, gekenmerk deur 'n groot verskil tussen die negatief-gelaaide en positief-gelaaide elektroliete in die bloed)

- *Antivirale middels* soos Sidovudien (wat gebruik word om infeksie wat deur MIV veroorsaak word, te behandel): Parasetamol, soos in COMPRAL® PAIN POWDERS, kan die metabolisme van sidovudien vertraag en ernstige toksiese skade aan die lewer veroorsaak.
- *Probenesied*: Vooraf-behandeling met probenesied kan die opruiming van COMPRAL® PAIN POWDERS verminder en die plasma halfleeftyd verhoog.
- *NSAIM's*: Langdurige gelyktydige gebruik van COMPRAL® PAIN POWDERS met NSAIM's verhoog die risiko van nierprobleme.
- *Alkohol:* Verminder die lewer se vermoë om parasetamol, soos in COMPRAL® PAIN POWDERS, te verwerk.
- *Chlooramfenikol:* Die gebruik van chlooramfenikol saam met parasetamol, soos in COMPRAL® PAIN POWDERS, kan die effek van chlooramfenikol verhoog.
- *Antibakteriese middels*: opruimingshalfleeftyd van kafeïen, soos in COMPRAL® PAIN POWDERS, verhoog en opruiming verminder wanneer dit saam met siprofloksasien, enoksasien en pipemidiese suur toegedien word. Enoksasien het die grootste remmende effek op die opruiming gehad.
- *Antidepressante*: Daar is aangemeld dat fluvoksamien die effekte van kafeïen, soos in COMPRAL® PAIN POWDERS, aansienlik verhoog.
- *Anti-epileptiese middels*: Die effek van kafeïen, soos in COMPRAL® PAIN POWDERS, kan verhoog word. Karbamasepien of valproaatsuur het geen effek op kafeïen, soos in COMPRAL® PAIN POWDERS, nie.
- *Metoksaleen* (gebruik om psoriase te behandel): Kan die opruiming van kafeïen, soos in COMPRAL® PAIN POWDERS, uit u liggaam verminder.
- *Geslagshormone*: Daar is aangemeld dat die opruiming van kafeïen verminder word en die gevolge daarvan verhoog word by vroue wat orale voorbehoedmiddels gebruik. Hierdie effek is ook aangemeld by postmenopousale vroue wat estrogeen neem as hormoonvervangingsterapie.

- *Simpatomimetika*: Daar is aangemeld dat die gebruik van kafeïen saam met efedrien beduidende kardiovaskulêre, metaboliese en hormonale reaksies veroorsaak, insluitend verhoogde sistoliese bloeddruk en hartspoed, en verhoogde vastende glukose en insulien.
- *Litium:* Kafeïen, soos in COMPRAL® PAIN POWDERS, kan die uitskakeling van litium uit die liggaam verhoog. Dit kan die effekte van litium verbeter. Daarom word gepaardgaande gebruik nie aanbeveel nie.
- *Allopurinol (medisyne wat gebruik word om jig te behandel):* Daar is aangemeld dat allopurinol die effekte van kafeïen, soos in COMPRAL® PAIN POWDERS, verhoog.
- *Simetidien (medisyne wat gebruik word vir sooibrand, maagsere, verhoogde suurproduksie en ander gepaardgaande simptome):* Daar is aangemeld dat simetidien die effekte van kafeïen, soos in COMPRAL® PAIN POWDERS, verhoog.

COMPRAL® PAIN POWDERS met kos, drank en alkohol

Vermy oormatige inname van kafeïen (bv. koffie, tee en sekere geblikte drankies) terwyl u COMPRAL® PAIN POWDERS neem.

Indien u aspirien saam met alkohol neem, kan dit die risiko van maag- en dermbloeding verhoog.

Swangerskap, borsvoeding en vrugbaarheid

Die gebruik van COMPRAL® PAIN POWDERS tydens swangerskap en borsvoeding word nie aanbeveel nie.

Indien u swanger is, of borsvoed, dink u is dalk swanger of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u COMPRAL® PAIN POWDERS neem.

COMPRAL® PAIN POWDERS moet nie gedurende die eerste en derde trimester van swangerskap geneem word nie, behalwe onder die advies en toesig van 'n mediese dokter. Gereelde gebruik van NSAIM's soos COMPRAL® PAIN POWDERS gedurende die derde trimester van swangerskap, kan lei tot voortydige sluiting van die fetale *ductus arteriosus in utero*, en moontlik aanhoudende pulmonale hipertensie van die pasgeborene.

Die aanvang van kraam kan vertraag word, en die duur daarvan kan verleng word, met 'n verhoogde risiko van bloedingsneiging by beide die moeder en kind. Indien die verwagte voordeel

vir die moeder groter is as die moontlike risiko vir die fetus, moet die laagste effektiewe dosis en die kortste duur van behandeling oorweeg word.

Kafeïen, soos in COMPRAL® PAIN POWDERS, word nie aanbeveel vir gebruik tydens swangerskap nie as gevolg van die moontlike verhoogde risiko van spontane aborsie wat verband hou met kafeïen-gebruik.

COMPRAL® PAIN POWDERS word nie aanbeveel vir gebruik tydens borsvoeding nie. Aspirien word in lae konsentrasies in borsmelk uitgeskei. Daar is onvoldoende inligting oor die effekte van aspirien by lae konsentrasie by babas. Behandeling moet tydens laktasie vermy word as gevolg van die moontlike risiko van Reye se sindroom en die potensiële verswakking van bloedplaatjie-funksie by die baba. Parasetamol word in borsmelk uitgeskei, maar nie in 'n beduidende hoeveelheid teen aanbevole dosisse nie. Kafeïen in borsmelk kan moontlik 'n stimulerende effek op borsvoedende babas hê, maar beduidende toksisiteit is nie waargeneem nie.

Bestuur en gebruik van masjinerie
COMPRAL® PAIN POWDERS kan newe-effekte veroorsaak, soos duiseligheid en vertigo (sensasie van swaai of vinnig draai). U moet nie bestuur of masjinerie gebruik indien u hierdie effekte ervaar nie.

3. Hoe om COMPRAL® PAIN POWDERS te neem
Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie.

Neem altyd COMPRAL® PAIN POWDERS presies soos beskryf in hierdie biljet of soos u dokter of apteker of verpleegkundige u ingelig het. Raadpleeg u dokter of apteker of verpleegkundige indien u nie seker is nie.

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

Indien u meer COMPRAL® PAIN POWDERS neem as wat u moes

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.

Parasetamol

U sal so gou moontlik gespesialiseerde behandeling benodig. 'n Vertraging in die aanvang van behandeling kan beteken dat teenmiddel (medisyne om die oordosis teë te werk) té laat gegee word om effektief te wees.

Gewoonlik kan lewerskade eers bevestig word nadat die tyd vir effektiewe behandeling verby is.

U kan geneig wees tot parasetamol-vergiftiging indien u herhaalde hoë dosisse (meer as 5-10 g/dag) van COMPRAL® PAIN POWDERS vir 'n paar dae neem, indien u ly aan chroniese alkoholisme, chroniese lewersiekte, VIGS, wanvoeding, en indien u medisyne gebruik soos barbiturate (vir angs, slapeloosheid en stuipaanvalle), isoniasied (vir tuberkulose), rifampisien (vir tuberkulose), fenitoïen (vir stuipaanvalle) en karbamasepien (vir stuipaanvalle).

Simptome van parasetamol-oordosering wat in die eerste 24 uur gesien word, is:

- bleek vel
- naarheid
- braking
- verlies aan eetlus
- buikpyn

Ligte simptome gedurende die eerste twee dae van akute vergiftiging, weerspieël nie die potensiële erns van die oordosis nie.

Ander simptome is:

- Lewerskade of besering 12 tot 48 uur na die neem van COMPRAL® PAIN POWDERS, maar kan soms vertraag wees.
- Abnormaliteite van glukose-afbreek
- Oortollige hoeveelheid suur in die bloed.
- Lewerskade wat kan lei tot siektes van die brein, koma en dood.
- Hartdisritmieë (onreëlmatige hartslag)
- Inflammasie van die pankreas
- Serebrale edeem (swelling van die brein) en nie-spesifieke miokardiale depressie

- Akute nierversaking

N-asetielsisteïen moet so gou as moontlik aan alle gevalle van vermoedelike oordosis gegee word, verkieslik binne 8 uur na oordosering, hoewel behandeling tot 36 uur na oordosering steeds voordelig kan wees, veral as meer as 150 mg/kg parasetamol geneem is.
IV (via die aar): 'n Aanvanklike dosis van 150 mg/kg N-asetielsisteïen in 200 ml dekstrose-inspuiting, binneaars (IV) toegedien oor 15 minute, gevolg deur 'n infusie van 50 mg/kg in 500 ml dekstrose-inspuiting oor die volgende 4 uur en dan 100 mg/kg in 1 000 ml oor die volgende 16 uur. **Die volume binneaarse vloeistowwe moet vir kinders aangepas word.**
Mondelings (per mond) nie die behandeling van keuse nie: 140 mg/kg opgelos in water kan aanvanklik geneem word, gevolg deur 70 mg/kg oplossing elke vier (4) uur vir sewentien (17) dosisse.

Aspirien
Simptome van aspirien-oordosering sluit in:

- duiseligheid
- tinnitus (gelui in die ore) of doofheid
- vertigo (verlies aan balans)
- sweet
- naarheid of braking
- verstandelike verwarring
- verhoogde asemhalingstempo (aantal asemhalings per minuut)
- hiperventilasie (vinnige asemhaling)
- warm hande en voete met vinnige polsslag
- verhoogde suur in die bloed,
- toename in ketone in die bloed
- verminderde funksionering van die sentrale senuweestelsel.

By kinders kan ernstige tekens van oordosering vinnig ontwikkel.
Ongewone kenmerke sluit in braking van bloed, hoë liggaamstemperatuur, lae bloedsuiker, lae kaliumbloedvlak, lae bloedplaatjie-bloedtelling, vertraagde bloedstolling, bloedvloei-ontwrigting, nierversaking en nie-hartverwante oormaat vloeistof in die longe. Sentrale senuweestelsel

kenmerke, insluitend verwarring, disoriëntasie, koma en onwillekeurige sametrekking van spiere, kom minder voor by volwassenes as by kinders.

In die geval van oordosering, raadpleeg 'n dokter of neem die pasiënt onmiddellik na die naaste hospitaal. Gespesialiseerde behandeling is so gou moontlik noodsaaklik.

Kafeïen

Simptome van kafeïen-oordosering sluit in:

- epigastriese pyn (pyn in die boonste deel van die buik)
- braking
- diurese (verhoogde urinering)
- blosing van die gesig ('n onwillekeurige rooiheid van die gesig)
- hartdisritmie
- rusteloosheid
- opgewondenheid
- geïrriteerdheid
- angs
- stuiptrekkings (stuipaanvalle)
- spierbewing
- tinnitus (gelui in die ore)
- visuele kol versteurings
- verhoogde tempo of ritme van hartklop
- abnormale hartkloppings.

In die geval van oordosering, raadpleeg 'n dokter of neem die pasiënt onmiddellik na die naaste hospitaal. Gespesialiseerde behandeling is so gou moontlik noodsaaklik.

Indien u vergeet om 'n dosis COMPRAL® PAIN POWDERS te neem

Moenie 'n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

4. Moontlike newe-effekte

COMPRAL® PAIN POWDERS kan newe-effekte hê.

Nie alle newe-effekte wat vir COMPRAL® PAIN POWDERS aangemeld is, word by hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak of indien u ongewenste gevolge ervaar

terwyl u COMPRAL® PAIN POWDERS neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak gebruik van COMPRAL® PAIN POWDERS en lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:

- Koors, veluitslag, swelling van die limfknope en/of swelling van die gesig (ook bekend as GRESS). Die uitslag kan rooi of jeukerig wees met swelling, maar kan soms ernstiger wees en gepaard gaan met koors en maagsere of absesse.
- Blase op u vel of binne-in u mond, neus, vagina of boude.
- Die voorkoms van 'n veluitslag of sonbrand wanneer u buite was (selfs op 'n bewolkte dag).
- Ander allergiese reaksies soos jeukerigheid, of hygende asemhaling, hoes of moeilike asemhaling, of swelling van die lippe en tong.
- U enige bloeding van u maag ervaar (simptome kan bloed in u stoelgang of braaksel insluit)
- U 'n toename in die aantal neusbloeding of kneusplekke ervaar.
- U gelui in u ore of tydelike gehoorverlies ervaar.
- U enige waterretensie ervaar.
- Wanneer dit by kinders gebruik word, vind veranderinge in gedrag plaas, naarheid en braking kom voor (dit kan vroeë tekens van Reye se sindroom wees).
- Ernstige velreaksies soos swelling, jeukerigheid, rooi erge uitslag, veral dié wat u hele liggaam bedek (verskyn as allergiese opwellings). Sien afdeling 2 (Waarskuwings en voorsorgmaatreëls, *Wees veral versigtig met COMPRAL® PAIN POWDERS*).

Hierdie is baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige reaksie op COMPRAL® PAIN POWDERS gehad. U sal dalk dringende mediese hulp of hospitalisasie benodig.

Lig u dokter in indien u enige van die volgende opmerk:

Minder gereeld:

Parasetamol

- Bloedverwante reaksies, insluitend lae bloedplaatjietelling, gebrek aan witbloedselle en 'n tipe bloedarmoede waarin die rooibloedselle, witbloedselle en bloedplaatjies almal in getal verminder word.
- Piroglutamien suur-urien ('n oorerflike afwyking van aminosuurmetabolisme)
- Gehoorverlies
- Veluitslag en ander allergiese reaksies soos jeukerigheid, of hygende asemhaling, hoes of moeilike asemhaling, of swelling van die lippe, tong en gesig. Die veluitslag kan rooi of jeukerig wees met swelling, maar kan soms meer ernstig wees en gepaard gaan met koors en sere of absesse.
- Lewerprobleme (geel oë en vel, naarheid, maagpyn).

Frekwensie onbekend:

Parasetamol

- Geneesmiddel-geïnduseerde hipersensitiwiteitsindroom (ernstige reaksie wat gewoonlik gekenmerk word deur koors, uitslag en veelvuldige orgaanversaking).
- Nier probleme
- Hoë bloeddruk
- Inflammasie van die pankreas
- Area-spesifieke geneesmiddel-uitslag (dit is dermatologiese manifestasies van medisynereaksies wat dikwels op dieselfde plek voorkom by herblootstelling aan 'n medisyne).

Aspirien

- Bloed- en limfstelselafwykings: Langdurige bloedingstyd, bloedarmoede, bloeddiskrasie, trombositopenie
- Immuunstelselafwykings: Hipersensitiwiteitsreaksies
- Metabolisme en voedingsafwykings: Natriumretensie en vloeistofretensie
- Oor- en doolhofversteurings: Tydelike gehoorverlies, tinnitus
- Senuweestelselafwykings: Duiseligheid, aseptiese breinvliesontsteking (inflammasie van die weefsels rondom die brein en rugmurg) en hoofpyn
- Kardiovaskulêr: Swelling, hoë bloeddruk, hartversaking

- Respiratoriese, torakale en mediastinale afwykings: Probleme met asemhaling of hygende asemhaling, verergering van asma.
- Gastro-intestinaal: Sere in maag of duodenum, gastro-intestinale bloeding, wat soms die dood kan veroorsaak. Naarheid, braking, diarree, winderigheid, hardlywigheid, slegte spysvertering, buikpyn, stoelgang wat verteerde bloed bevat, braking van bloed, mondsere en koorsblare, verergering van inflammasie van die dikderm en inflammatoriese siekte wat die maag en dermkanaal aantas, inflammasie van die maag.
- Hepato-biliêr: Verhoogde lewerensieme, Reye se sindroom (by kinders en adolessente onder die ouderdom van 18 jaar), wat dodelik kan wees, wat brein- en lewerskade veroorsaak. Kom gewoonlik voor by kinders wat 'n onlangse virusinfeksie gehad het, soos waterpokkies of griep.
- Velreaksies: Verhoogde knoppe wat vloeistof bevat, insluitend Stevens-Johnson se sindroom (seldsame velafwyking) en ernstige velreaksie.
- Nier- en urinêre afwykings: Nierprobleme, verhoogde uriensuur in urien. Langdurige gebruik van hoë dosisse kan lei tot nierpapillêre nekrose ('n tipe skade wat in u niere voorkom).

Kafeïen

- Gastro-intestinale afwykings: Naarheid, verhoogde maagafskeidings en maagsere.
- Hartafwykings: Hartkloppings, tagikardie (abnormaal vinnige hartklop).
- Psigiatriese versteurings: Probleme om te slaap, rusteloosheid, angs, prikkelbaarheid en senuweeagtigheid.
- Senuweestelselafwykings: Duiseligheid, hoofpyn, stuiptrekkings (onbeheerbare skudding wat vinnig en ritmies is, met die spiere wat herhaaldelik saamtrek en ontspan), opgewondenheid, verlies van een of meer tipes sensoriese persepsie en spierbewing (onwillekeurige bewegings).
- Vertigo (sensasie van draai of swaai).
- Tinnitus (gelui in die ore).
- Verhoogde urinering.

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte

Indien u enige newe-effekte ervaar, raadpleeg u dokter of apteker, of verpleegkundige. U kan ook newe-effekte by SAHPRA aanmeld via die vorm **"6.04 Adverse Drug Reaction Reporting Form"** wat aanlyn onder SAHPRA se publikasies gevind kan word: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van COMPRAL® PAIN POWDERS. U kan dit ook by Adcock Ingram Limited aanmeld deur die volgende e-posadres te gebruik: Adcock.AEReports@adcock.com.

5. Hoe om COMPRAL® PAIN POWDERS te bêre

Bêre alle medisyne buite bereik van kinders.
Bêre in lugdigte houers, beskerm teen lig teen of benede 25 °C.
Moenie in 'n badkamer bêre nie.
Moenie gebruik ná die vervaldatum wat op die polipapier of kartonboksie vermeld word nie.
Neem alle ongebruikte medisyne terug na u apteker.
Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat COMPRAL® PAIN POWDERS bevat

Die aktiewe bestanddele is:

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

Die ander bestanddeel

Kolloïdale Watervrye Silika

Hoe COMPRAL® PAIN POWDERS lyk en die inhoud van die verpakking

COMPRAL® PAIN POWDERS is 'n fyn, wit, kristallyne poeier met 'n effense suur reuk
846 mg poeier word verpak in polipapiersakkies in verpakkings van 2, 10, 24, 38 en in enkeldosisse.

Nie alle verpakkingsgroottes word dalk bemark nie.

Houer van Sertifikaat van Registrasie

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