

SCHEDULING STATUS: S0

**GRAND-PA HEADACHE TABLETS
GRAND-PA HEADACHE POWDERS**

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

GRAND-PA HEADACHE TABLETS

(Aspirin 226,8 mg, Paracetamol 162,0 mg, Caffeine 32,4 mg)

GRAND-PA HEADACHE POWDERS

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

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

GRAND-PA is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use GRAND-PA carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share GRAND-PA with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet

1. What GRAND-PA is and what it is used for
2. What you need to know before you use GRAND-PA
3. How to use GRAND-PA
4. Possible side effects
5. How to store GRAND-PA
6. Contents of the pack and other information

1. What GRAND-PA is and what it is used for

GRAND-PA HEADACHE TABLETS: Each tablet contains:

Aspirin	226,8 mg
Paracetamol	162,0 mg
Caffeine	32,4 mg

Inactive ingredients: Colloidal silicon dioxide, microcrystalline cellulose and stearic acid. Sugar free.

GRAND-PA HEADACHE POWDERS: Each powder contains:

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

Inactive ingredients: Magnesium stearate / Silicon dioxide. Sugar free.

GRAND-PA is recommended for the symptomatic relief of mild to moderate pain and fever such as headaches, toothache, colds and flu.

2. What you need to know before you use GRAND-PA

Do not take GRAND-PA if you:

- If you are hypersensitive (allergic) to aspirin, other salicylates (the class of medicines to which aspirin belongs), paracetamol, caffeine or any of the other ingredients of GRAND-PA (see Contents of the pack and other information).
- If you have a history of hypersensitivity reactions e.g. 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, rhinitis, irritation and inflammation of the mucous membranes inside the nose, urticaria (hives), nasal polyps (sac like growths of inflamed tissue lining the nose or sinuses) when you take aspirin or non-steroidal anti-inflammatory drugs (NSAIDs).
- If you are taking medicines to reduce blood clotting.
- If you have or ever had a problem of your blood not clotting properly.
- If you 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).
- If you have severe kidney damage, liver impairment or heart failure.
- are in the last 3 months of pregnancy.

Warnings and precautions

- if your symptoms do not improve within 10 days of continuous use. Please consult your doctor.
- when giving to children because aspirin may cause Reye's syndrome. Reye's syndrome is a rare disease, which may cause death. For this reason, do not give GRAND-PA to children under 16 years of age unless prescribed by a doctor.
- if you have a history of high blood pressure or heart disease, as you may experience water retention and swelling.
- if you are elderly, as you may experience an increased frequency of side effects especially stomach and intestinal bleeding, which may cause death.
- if stomach ulcer, damage or bleeding occurs while taking GRAND-PA, stop treatment and consult a doctor or medical practitioner.
- if you have a history of stomach and intestinal diseases e.g. inflammatory disease of the stomach and intestine, stomach pushing up into the chest, digestive disorder which affects the lower gut sphincter and vascular malformation of the gut, as these conditions may worsen.
- if you experience serious skin reactions while taking GRAND-PA. Discontinue treatment at the first appearance of skin rash, lesions or any other sign of hypersensitivity.
- Very rare cases of serious skin reactions have been reported.

Pregnancy, breastfeeding and fertility

GRAND-PA is not for use during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery. Mothers using GRAND-PA should not breastfeed their babies as aspirin passes into breast milk. Consult your doctor or pharmacist for further information if you are pregnant or breast-feeding.

Other medicines and GRAND-PA

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

3. How to use GRAND-PA

Always take GRAND-PA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Use the lowest effective dose for the shortest possible duration of treatment.

TABLETS: ADULTS: Take two tablets with water every three hours.

POWDERS: ADULTS: Take one powder with water every three hours. Do not use more than one powder every 3 to 4 hours if necessary and not more than 6 powders during a 24-hour period.

Do not take with other aspirin or paracetamol containing products.

If you take more GRAND-PA than you should:

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

ASPIRIN

You may experience the following symptoms related to aspirin overdose:

- dizziness
- ringing in the ears
- sweating
- nausea
- vomiting
- mental confusion
- breathing faster or deeper than normal,
- increase in blood pH
- 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.

PARACETAMOL

You may be prone to paracetamol poisoning if you take repeated high doses (greater than 5 - 10 g/day) of paracetamol for several days, in chronic alcoholism, chronic liver disease, AIDS, malnutrition, and if you use drugs 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 and likely to remain for a week or more are:

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

Other symptoms are:

- liver damage or injury 12 to 48 hours after taking GRAND-PA
- abnormalities of glucose breakdown
- excess quantity of acid in the blood
- liver damage which may progress to disease of the brain, coma and death
- swelling on the brain
- reduced contractions of the heart muscle may also occur

You may also develop:

- acute kidney failure with acute death of kidney tubule cells even in the absence of severe liver damage
- changes in heart rate or rhythm

The symptoms you experience during the first 2 days of acute poisoning do not reflect the potential seriousness of the overdosage which you may experience later. In the event of overdosage consult a doctor go to the nearest hospital immediately. You will require specialised treatment as soon as possible. If you have taken about 7,5 g of paracetamol in the preceding 4 hours you should undergo gastric lavage (stomach pumping). An antidote such as acetylcysteine or methionine may be necessary to use. Acetylcysteine should be taken by direct venous injection as soon as possible. If you have taken 5 - 10 grams or more of paracetamol (or if a child has had more than 140 mg/kg) within the preceding 4 hours, you should have the stomach emptied by lavage (pumping). Vomiting may be adequate for children, and a single dose of 50 g activated charcoal must be taken via the lavage tube. If you are prone to paracetamol poisoning (see above), and take amounts smaller than this, you may still require treatment. In patients who are partially conscious or unconscious an emergency procedure with a tube placed into the windpipe) should be conducted before stomach pumping to avoid blockage of the airways.

Acetylcysteine:

Acetylcysteine should be given as soon as possible, preferably within 8 hours of overdosage.

IV: An initial dose of 150 mg/kg in 200 ml glucose injection, given intravenously over 15 minutes, followed by an intravenous infusion of 50 mg/kg in 500 ml of glucose injection over the next 4 hours and then 100 mg/kg in 1 000 ml over the next 16 hours. The volume of intravenous fluids should be modified for children.

Orally: 140 mg/kg as a 5 % solution initially, followed by a 70 mg/kg solution every 4 hour for 17 doses. Acetylcysteine is effective if administered within 8 hours of overdosage.

CAFFEINE

If you take large doses, you may experience the following symptoms related to caffeine overdose:

- restlessness
- excitement
- anxiety
- muscle tremor
- ringing in the ears
- visual spot disturbances
- increased rate or rhythm of heartbeat
- abnormal heartbeats

If you forget to take a dose of GRAND-PA:

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

4. Possible side effects

GRAND-PA can have side effects. Not all side effects reported for GRAND-PA are included in this leaflet. Should your general health worsen while receiving GRAND-PA, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happen, stop taking GRAND-PA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- yellowing of the skin and eyes, also called jaundice

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to GRAND-PA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- You experience unexplained bruising or bleeding.
- Prolonged bleeding time.
- You have any bleeding from your stomach (symptoms can include blood in your stools or vomit).

These are all serious side effects. You may need urgent medical attention.

The following side effects may occur, but the frequency is unknown:

ASPIRIN:

- Cardiovascular: Swelling, high blood pressure, heart failure.
- Gastrointestinal: Ulcers in stomach or duodenum, gastrointestinal bleeding, which can sometimes cause death. Nausea, vomiting diarrhea, 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.
- If you are an asthmatic you may show notable sensitivity to aspirin which may trigger various allergic reactions and which may include skin flare-ups, sudden recurrence of breathing difficulties and shortness of breath.
- Dizziness may occur in some cases.

PARACETAMOL:

- Inflammation of the pancreas, skin rashes and other allergic reactions may occur. The rash may be red or itchy with swelling but sometimes may be more serious and accompanied by fever and ulcers or abscesses.
- 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.

CAFFEINE:

- Nausea, headache, difficulty sleeping, increased stomach secretions and stomach ulcers.

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

Reporting of side effects

If your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine. Phone: 0861-555-777; Website: <http://www.paediatrics.uct.ac.za/poisons-information-centre>; Email: poisonsinformation@uct.ac.za and refer patient to nearest Emergency Medical Centre for management and expert treatment. This should happen even in patients without symptoms or signs of overdose due to the risk of delayed liver damage.

5. How to store GRAND-PA

KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.

Store in a cool dry place, at or below 25 °C.

Do not store in a bathroom.

Do not use after the expiry date stated on the sachet, wrapper 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 GRAND-PA contains

GRAND-PA HEADACHE TABLETS

(Aspirin 226,8 mg, Paracetamol 162,0 mg, Caffeine 32,4 mg)

GRAND-PA HEADACHE POWDERS

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

What GRAND-PA looks like and contents of the pack

GRAND-PA HEADACHE TABLETS: Round bisected white tablet embossed with chevron.

GRAND-PA HEADACHE POWDERS: Fine, white powder.

GRAND-PA HEADACHE TABLETS: In packs of 2, 10, 24, 38, 50 and 76 tablets.

GRAND-PA HEADACHE POWDERS: Wrappers of 848 mg in packs of 10, 12, 20, 25 and 38, stick packs of 848 mg (Magnesium stearate) / 847 mg (Silicon dioxide) in packs of 5, 12, 25, 38 and sachets of 848 mg in single doses.

Holder of certificate of registration

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This leaflet was last revised in

The date of registration of the medicine (GRAND-PA HEADACHE POWDERS): 26 April 1983

The date of registration of the medicine (GRAND-PA HEADACHE TABLETS): 10 August 1981

Date of the most recent amendment to the professional information as approved by the Authority:
5 May 2024 (routine safety update).

Registration Number

GRAND-PA HEADACHE TABLETS: P/2.9/22

GRAND-PA HEADACHE POWDERS: B/2.9/1113

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