

SCHEDULING STATUS: S0

PROPRIETARY NAME AND DOSAGE FORM

GRAND-PA HEADACHE TABLETS

GRAND-PA HEADACHE POWDERS

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 10 days.

COMPOSITION

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. Sugar free.

APPROVED INDICATIONS AND USE

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

INSTRUCTIONS BEFORE TAKING GRAND-PA

Do not take GRAND-PA:

- 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 "COMPOSITION").
- 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.
- If you have or ever had gout
- If you are in the last three months of pregnancy or breastfeeding.

Take special care with GRAND-PA:

- to not exceed the recommended daily dose as it may cause serious harm to your liver.
- if your symptoms do not improve within 10 days of continuous use. Please consult your doctor.
- to always use the lowest effective dose to relieve symptoms for the shortest period of time.
- Contains paracetamol. Do not use this medicine if you are taking any other prescription or non-prescription medicines containing paracetamol to treat pain, fever, symptoms of cold and flu, or to aid sleep.
- **Check with your doctor before use if you:**
 - have liver or kidney problems
 - are underweight or malnourished
 - regularly drink alcohol

You may need to avoid using GRAND PA altogether or limit the amount of paracetamol you take.

- **Check with your doctor before use** if you have a severe infection, are severely malnourished, are severely underweight, or are a chronic heavy alcohol user, as this 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

- are taking pain relievers or anti-inflammatory medicines
- feel thirsty or have a dry mouth following sickness, such as diarrhea or vomiting, which could reduce the amount of water in the body.
- are diagnosed with glucose-6-phosphate dehydrogenase (G6PD) deficiency
- if you experience any unusual bleeding, as this may be caused by aspirin
- 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 or diabetes, 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.

Please see a doctor if cough persists, or if it is accompanied by high fever, skin rash or persistent headache.

Taking GRAND-PA with food or drink:

Avoid excessive intake of caffeine (e.g. coffee, tea and some canned drinks) while taking GRAND-PA.

If you take aspirin with alcohol, it could increase the risk of gastrointestinal bleeding.

Human Reproduction:

Do not take GRAND-PA during pregnancy and breastfeeding.

If you are pregnant or breastfeeding your baby while taking GRAND-PA, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

This medicine is not recommended during pregnancy. It is especially important not to take this medicine during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery.

Do not take this medicine if you are breast feeding as it might be harmful for your infant. Tell a doctor if you are breast feeding.

Driving and Using machinery:

If you take GRAND-PA it may have a minor/moderate influence on your ability to drive and use machines, therefore take with caution.

Using other medicines with GRAND-PA:

Always tell your healthcare professional 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 GRAND-PA:

- NSAID's (Non-steroidal anti-inflammatory drugs - a class of medicines that provides pain-relieving, fever reducing and anti-inflammatory effects, e.g. ibuprofen). If you use two or more medicines in this class you could experience an increase in side effects.
- Corticosteroids (medicines used to reduce inflammation) can cause an increased risk of stomach ulcers.
- GRAND-PA may enhance the effects of anticoagulants (medicines used to thin blood e.g. warfarin) and anti-diabetic medicines (sulphonylureas e.g. glibenclamide).
- Anti-platelet agents (medicines that decrease formation of blood clots) and SSRI's (used to treat depression, anxiety disorders and some personality disorders) may increase the risk of stomach and intestinal bleeding.

- GRAND-PA may diminish the effects of medicines used in the treatment of gout (e.g. probenecid and sulfinpyrazone).
- Barbiturates (CNS depressants) and other sedatives (medicines which cause drowsiness) may mask the respiratory symptoms of aspirin (contained in GRAND-PA) overdose.
- Some medicines used to treat high blood pressure
- Diuretics to increase urine production and reduce excess fluid
- Methotrexate to treat some kinds of cancer, arthritis or psoriasis
- Antacid which neutralizes stomach acidity
- Anticonvulsants such as valproate and phenytoin
- Alcohol

INSTRUCTIONS ON HOW TO TAKE 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.

Do not take more than 12 tablets in 24 hours.

Do not take more frequently than every 3 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 overdose, 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, deafness
- sweating
- nausea
- vomiting
- mental confusion
- breathing faster or deeper than normal,
- warm hands and feet with rapid pulses
- 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.

Other less common features include vomiting blood, high fever, low blood glucose levels, low blood potassium levels, low blood platelet count, increased clotting time, blood clots, kidney failure, blockage of blood vessels to lungs. Central nervous system features include confusion, disorientation, coma and convulsions which are less common in adults than in children.

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 overdose 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 overdose which you may experience later.

In the event of overdose 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.

N-acetylcysteine:

N-acetylcysteine should be given as soon as possible, preferably within 8 hours of overdose.

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. N-acetylcysteine is effective if administered within 8 hours of overdose.

CAFFEINE

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

- Stomach pains, vomiting, passing urine frequently,
- Restlessness, excitement, anxiety, convulsions
- 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.

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:

- you experienced an allergic reaction such as skin rashes and itching, or wheezing, coughing or difficulty breathing, or swelling of the lips, tongue and face
- fainting,

- yellowing of the skin and eyes, also called jaundice.
- 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 swelling or water retention.
- When used in children, changes in behaviour, nausea and vomiting occur (it could be the early signs of Reye's syndrome)
- You experienced a skin rash or peeling, or mouth ulcers
- You have experienced breathing problems with aspirin or non-steroidal anti-inflammatories, and experience a similar reaction with this product
- You experience unexplained bruising or bleeding.
- Prolonged bleeding time

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.

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.
- Kidney and Urinary Disorders: Kidney problems, increased uric acid in urine.
- 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, palpitations, restlessness, anxiety, irritability, nervousness, increased stomach secretions and stomach ulcers.

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

STORING AND DISPOSAL INFORMATION OF GRAND-PA:

KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.

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

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).

PRESENTATION OF GRAND-PA HEADACHE POWDERS

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

GRAND-PA HEADACHE POWDERS: Wrappers of 848 mg in packs of 10, 12, 20, 25 and 38 and sachets of 848 mg in single doses.

IDENTIFICATION OF GRAND-PA

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

GRAND-PA HEADACHE POWDERS: Fine, white powder.

REGISTRATION NUMBER

GRAND-PA HEADACHE TABLETS: P/2.9/22

GRAND-PA HEADACHE POWDERS: B/2.9/1113

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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DATE OF PUBLICATION

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

The date of registration of the medicine (GRAND-PA HEADACHE TABLETS): 09 October 1981

Date of the most recent amendment to the patient information leaflet as approved by the Authority: 30 April 2019.

SCHEDULING STATUS AND REGISTRATION NUMBERS ALLOCATED BY OTHER NATIONAL MEDICINES REGULATORS

GRAND-PA HEADACHE POWDERS:	GRAND-PA HEADACHE TABLETS:
NS0 Namibia Reg No 11/2.9/0186	NS0 Namibia Reg No 11/2.9/0187
S4 Botswana Reg No BOT1803248	S4 Botswana Reg No B9304615
GSL Malawi Reg No PMPB/PL260/23	Mozambique Reg No 2592
Mozambique Reg No 2793	GS Zambia Reg No 025/017
GS Zambia Reg No 025/019	HR Zimbabwe Reg No 2013/2.2/4787
HR Zimbabwe Reg No 74/2.2/0440	