

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

PANADO PLUS capsules

Ibuprofen 200 mg and Paracetamol 250 mg

Sugar free

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

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

- Keep this leaflet. You may need to read it again.
- Do not share PANADO PLUS 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 PANADO PLUS is and what it is used for
2. What you need to know before you take PANADO PLUS
3. How to take PANADO PLUS
4. Possible side effects
5. How to store PANADO PLUS

6. Contents of the pack and other information

1. What PANADO PLUS is and what it is used for

The active ingredient ibuprofen belongs to a group of medicines called anti-inflammatory pain killers. The active ingredient paracetamol acts as an analgesic (painkiller) and as an antipyretic (reduces body temperature when fever is present). PANADO PLUS is used for the relief of headache from musculo-skeletal origin, feverishness, muscular, menstrual and dental pain.

2. What you need to know before you take PANADO PLUS

Do not take PANADO PLUS

- If you are hypersensitive (allergic) to paracetamol, ibuprofen or any of the other ingredients of PANADO PLUS (listed in section 6), or
- If you have problems with your liver function
- If you have heart failure
- If you have asthma or bronchospasm
- If you have a stomach ulcer or a history of such ulceration, bleeding ulcers or damage to the stomach lining
- If you have heart disease
- If you have bleeding disorders
- If you take medicines for thinning out the blood (oral anti-coagulants)
- If you have kidney failure
- If you are sensitive to aspirin or other NSAIDs
- 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.

Warnings and precautions

PANADO PLUS contains paracetamol which may be fatal in overdose. In the event of overdose or suspected overdose even if you are not showing or experiencing any symptoms, the nearest doctor, hospital or Poison Centre must be contacted immediately. Prompt specialized treatment is essential as soon as possible.

- Be sure to take the correct dosage of PANADO PLUS. Severe liver damage may occur if you take doses higher than those recommended.
- If pain or fever persists or gets worse at the recommended dosage, if new symptoms occur or if redness and swelling is present, please consult your doctor as these could be signs of a more serious condition.
- Do not use continuously for more than 10 days without consulting your doctor.
- Caution is required in patients with a history of hypertension and/or heart failure as fluid retention and oedema have been reported in association with PANADO PLUS® therapy. In view of the PANADO PLUS®'s inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.
- Excessive and prolonged use of this medicine may be dangerous.
- Patients suffering from liver and kidney disease should take PANADO PLUS under medical supervision.
- Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens - Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), have been reported in patients receiving paracetamol. If you experience any signs of serious skin reactions such as swelling, itching, red severe rash, stop using PANADO PLUS immediately and contact your doctor.
- If you are elderly as there is an increased risk of side-effects, especially bleeding which can be fatal.
- When gastrointestinal bleeding or ulceration occurs in patients receiving PANADO PLUS®, treatment with PANADO PLUS® should be stopped.
- If you have a history of gastrointestinal disease (e.g. ulcerative colitis, Crohn's disease, hiatus hernia, gastro-oesophageal reflux disease, angiodysplasia) as the condition may be worsened.
- Should be used with caution in patients with infection since symptoms such as fever and inflammation may be masked.
- If you develop a fever, skin rash, swelling of the lymph nodes and/or swelling of the face. This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

- Tell your doctor or health care provider if you are pregnant or plan to become pregnant. 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.

Other medicines and PANADO PLUS

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

- If you are taking Warfarin or other blood thinning medicines (anticoagulants) PANADO PLUS may increase the anticoagulant effect and there is an increased risk of bleeding if you take regular or high doses of paracetamol while on an oral anticoagulants.
- Corticosteroids, other anti-inflammatories and aspirin are medicines known to influence the effect of ibuprofen and increase the risk of gastrointestinal bleeding and ulceration.
- The use of two or more NSAIDs concomitantly could result in an increase in side effects.
- Medicines for mania or depression (e.g. lithium) – increase the amount of Lithium in the blood.
- Medicines to suppress the immune system (e.g. ciclosporin, tacrolimus) - increases the risk of adverse kidney effects.
- Methotrexate: Increased plasma concentrations of methotrexate
- Heart stimulants (e.g. glycosides) - increase the amount of glycosides in the blood.
- Medicines to reduce high blood pressure (e.g. ACE-inhibitors, beta-blockers) and diuretics (to help you pass urine) may have a reduced anti-hypertensive effect and may increase the risk of adverse kidney effects.
- Medicines for malaria (quinolines) - can cause seizures when used together
- Medicines for seizures (e.g. phenytoin) – NSAIDs increase their effects
- Medicine for diabetes (e.g. sulphonylurea) – NSAIDs may increase their effects

- Moclobemide (medicine used for depression) – the effects of NSAIDs may increase when used together
- Biphosphonates (medicine used in osteoporosis) – the risk of gastrointestinal bleeding and ulceration of NSAIDs is increased.
- Taking PANADO PLUS together with certain antiviral medicines such as Zidovudine can cause severe toxic damage to the liver.
- Mifepristone (for pregnancy termination) efficacy may be altered if used with NSAIDs or aspirin
- Oxypentifylline: The risk of gastrointestinal bleeding and ulceration associated with NSAID's is increased when used with oxypentifylline.
- Anti-platelet medicines and selective serotonin reuptake inhibitors (SSRIs): Increased risk of gastrointestinal bleeding.

Pregnancy, breastfeeding and fertility

The use of PANADO PLUS during pregnancy and breastfeeding is not recommended. Please consult your doctor, pharmacist or other healthcare professional before using this medicine.

If you are pregnant or breastfeeding, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking PANADO PLUS.

Driving and using machines

PANADO PLUS capsules lack significant sedative effects. However some people may suffer sedation. PANADO PLUS may also cause blurred vision.

It is not always possible to predict to what extent PANADO PLUS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which PANADO PLUS affects them.

3. How to take PANADO PLUS

Always take PANADO PLUS exactly as described in this leaflet or as your doctor or pharmacist or nurse have told you. Check with your doctor or pharmacist or nurse if you are not sure.

Always take PANADO PLUS as recommended and **do not exceed the recommended dose.**

Not recommended for children under twelve years. The usual dose is:

Adults and children over 12 years:

Two capsules every four hours, but not more than six capsules in twenty four hours.

Capsules are to be taken with food or after meals with sufficient water. Maximum treatment period 10 days.

Consult your doctor if no relief is obtained with the recommended dosage.

If you take more PANADO PLUS than you should

PANADO CAPSULES contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose even if you may not be showing or experiencing any symptoms, the nearest doctor, hospital or Poison Centre must be contacted immediately. Prompt specialised treatment is essential as soon as possible.

The initial symptoms of a paracetamol overdose (within the first 24 hours) may include pallor (pale appearance), nausea, vomiting, anorexia (loss of appetite) and abdominal pain (stomach ache).

Even though these initial symptoms may appear mild, paracetamol overdosage is a serious condition, as liver damage may only become apparent 12 to 48 hours after the paracetamol overdose.

The symptoms reported for overdosage of ibuprofen in adults and children are epigastric pain, nausea, heartburn and abdominal discomfort.

If you forget to take PANADO PLUS

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

4. Possible side effects

PANADO PLUS can have side effects.

Not all side effects reported for PANADO PLUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PANADO PLUS, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop using PANADO PLUS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the eyelids, face, tongue, throat or lips
- difficulty in breathing
- decrease in blood pressure (hypotension)
- Serious skin reactions such as swelling, itching, red severe rash especially those covering your whole body (appearing as allergic wheals), stop using PANADO PLUS immediately and contact your doctor.

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

Stop taking PANADO PLUS and call your doctor at once if you experience any of the following:

- Severe headache, high temperature, stiffness of the neck or intolerance to light
- nausea, upper stomach pain, itching, loss of appetite;
- dark urine, clay-coloured stools;
- jaundice (yellowing of the skin or eyes)
- Pass blood in your faeces (stools/motions)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds.
- Swelling of legs and ankles

The following side-effects have been reported, tell your doctor if you notice any of the following:

- If you have an increase in number of nose bleeds or unusual bleeding
- If you bruise more easily

- If you have more infections
- Impairment of kidney function and kidney failure and fluid retention
- Sudden decrease in the amount of urine
- Unusual tiredness or weakness
- Increase in blood pressure, heart failure
- Pale complexion, abnormalities of liver function tests, liver failure and inflammation of the liver.
- Blurred vision, ringing in the ear, sleeping difficulty, depression, nervousness, aseptic meningitis (inflammation of the tissues that cover the brain and spinal cord)
- Gastrointestinal system disorders such as nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia (indigestion), abdominal pain, gastritis (inflammation of the lining of the stomach) and inflammation of the pancreas
- Blood disorders like decrease in white blood cells, decrease in red blood cells and hypersensitivity reactions
- Other hypersensitivity reactions. Stevens-Johnson syndrome (a rare, serious disorder of the skin and mucous membranes) has been reported.
- Fever, skin rash, swelling of the lymph nodes and/or swelling of the face (also known as DRESS),

Reporting of side effects

If you get 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 publication:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of PANADO PLUS.

5. How to store PANADO PLUS

Store all medicines out of reach of children.

Store at or below 25 °C in a well closed container, protected from light.

Do not remove the blister from the carton until required for use.

Do not store in bathrooms.

Do not use this medicine after the expiry date stated on the label.

Return all unused medicine to your pharmacy. Do not dispose of unused medicine in drains or seweragesystems e.g. toilets.

6.Contents of the pack and other information

What PANADO PLUS contains

The active substances are ibuprofen and paracetamol.

Each PANADO PLUS capsule contains: Ibuprofen 200 mg and Paracetamol 250 mg.

The other ingredients are: Pregelatinized starch, microcrystalline cellulose, sodium stearyl fumarate, gelatin and titanium dioxide.

PANADO PLUS is sugar free.

What PANADO PLUS looks like and contents of the pack

A hard gelatin capsule with opaque, white body and cap, containing a white, granular powder. 'PANADOPLUS' is printed in red ink on the capsule.

Securitainers with 30 or 60 capsules; tracer packs with 20 or 60 capsules; blister pack with 20 or 100capsules.

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

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BOTSWANA REGISTRATION NUMBER:

30's in HDPE	BOT1502723 S3
60's in HDPE	BOT1502723A S3
20's in PP Tracer pack	BOT1502723B S3
60's in PP Tracer pack	BOT1502723C S3
100's in blister pack	BOT1502723D S3

NAMIBIA REGISTRATION NUMBER:

NS1 12/2.8/0247

Access to the corresponding Professional Information

The PI is included in the medicine package.