

SCHEDULING STATUS: **S0**

PANADO TABLETS, 500 mg tablets

Paracetamol

Sugar free

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

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

- Keep this leaflet. You may need to read it again.
- Do not share PANADO TABLETS with any other person.
- Ask your healthcare 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 TABLETS is and what it is used for
2. What you need to know before you take PANADO TABLETS
3. How to take PANADO TABLETS
4. Possible side effects
5. How to store PANADO TABLETS
6. Contents of the pack and other information

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

The active ingredient paracetamol acts as an analgesic (pain reliever) and as an antipyretic (reduces body temperature when fever is present).

PANADO TABLET is used for the relief of mild to moderate pain and fever (such as headaches, toothache and pain associated with cold and flu).

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

Do not take PANADO TABLETS:

- if you are hypersensitive (allergic) to paracetamol or any of the other ingredients of PANADO TABLETS (listed in section 6).
- if you have serious problems with your liver function.

Warnings and precautions

Take special care with PANADO TABLETS:

PANADO TABLETS contain paracetamol which may be fatal in overdose. In the event of overdose 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.

- Do not use continuously for more than 10 days without consulting the doctor.
- Do not take more PANADO TABLETS than recommended (see section 3, 'How to take PANADO TABLETS'). Concomitant use of PANADO TABLETS with other medicines containing paracetamol, such as flu and cold medicines should be avoided since high doses may lead to liver damage. Do not use more than one medicine containing paracetamol without talking to your doctor.
- In cases of high fever, signs of a secondary infection, or persistence of your symptoms for more than three days, consult your doctor or pharmacist.
- If you are suffering from liver problems including liver problems due to excessive alcohol consumption.
- If you are suffering from kidney problems.
- If you suffer from glucose-6-phosphate dehydrogenase deficiency (enzyme deficiency).
- If you have haemolytic anaemia (abnormal breakdown of red blood cells).
- If you regularly take large amounts of alcohol. Never take more than 2000 mg per day.
- Headaches caused by overuse of analgesics should not be handled by increasing the dose. In those cases, the use of analgesics should be taken after consulting a doctor.
- If you are an asthmatic and sensitive to aspirin (acetylsalicylic acid).

- When you are taking any medicine to treat epilepsy you should consult your doctor before taking PANADO TABLETS, because when used at the same time, it decreases the effectiveness and potentiates the risk of liver damage by paracetamol, especially in treatments when using high paracetamol doses.
- In case of dehydration or chronic malnutrition.
- Serious skin reactions 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) have been reported in patients receiving paracetamol. If you experience any signs of serious skin reactions such as swelling, itching, red severe rash, stop taking PANADO TABLETS immediately and contact your doctor (see section 4).

Children and adolescents

Do not give PANADO TABLETS to children under the age of 6 years. Paracetamol syrup should rather be considered for use if such a medicine is necessary.

Other medicines and PANADO TABLETS

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

- The risk of side effects with paracetamol (i.e., PANADO TABLETS) may be increased in patients taking other medicines that may be harmful to the liver or medicines that can influence the functioning of the liver.
- Metoclopramide or domperidone (medicines used to treat nausea and vomiting) may increase the absorption of paracetamol.
- Cholestyramine (a medicine used to lower blood cholesterol) reduces the absorption of paracetamol.
- Warfarin and other coumarin derivatives (medicines to thin the blood). PANADO TABLETS 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 anticoagulant.

PATIENT INFORMATION LEAFLET

- Antiepileptics medicine (medicines used to treat epilepsy) such as barbiturates or carbamazepine, fosphenytoin, phenytoin, phenobarbital, or primidone may increase liver toxicity.
- Medicines used to treat epilepsy and oral contraceptives, also known as ‘the pill’: The use of these medicines with paracetamol (i.e., PANADO TABLETS), may reduce the effectiveness of PANADO TABLETS.
- St. John’s wort and tricyclic antidepressants (medicines used to treat depression) may increase liver toxicity.
- Probenecid (a medicine used to treat high levels of uric acid in the bloodstream i.e., gout) may affect the excretion of paracetamol and plasma (blood) concentrations may be altered when taken together.
- Chloramphenicol (an antibiotic used to treat bacterial infections). The use of chloramphenicol with paracetamol (i.e., PANADO TABLETS) may extend the duration of action of chloramphenicol.
- Zidovudine (a medicine used to treat HIV (Human Immunodeficiency Virus) and AIDS(Acquired Immune Deficiency syndrome)). Prolonged concurrent use of PANADO TABLETS and zidovudine can cause neutropenia (low white blood cell count).
- Taking PANADO TABLETS together with certain antiviral medicines such as zidovudine and co-trimoxazole, can cause severe toxic damage to the liver.
- Interferon alfa (a medicine used to treat hepatitis B and C). The antiviral effect of interferon alfa may be increased if taken with PANADO TABLETS.
- Salicylates (e.g., aspirin (acetylsalicylic acid) or salicylamide (medicine used to treat fever or mild pain). Prolonged concurrent use of PANADO TABLETS with these medicines may increase the risk of adverse kidney effects.
- Isoniazid or rifampicin (medicines used to treat tuberculosis). The use of PANADO TABLETS and certain antibacterials used for the treatment of tuberculosis (a disease affecting the lungs) can cause toxic damage to the liver.
- Lamotrigine (a medicine used to treat epilepsy). The use of PANADO TABLETS together with lamotrigine may reduce the effectiveness of lamotrigine.
- Flucloxacillin (an antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe

renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of PANADO TABLETS are used.

If you are going to have any laboratory tests (such as a blood test, urine analysis, skin allergy test, etc.), you should tell your doctor that you are taking PANADO TABLETS as it could affect the results of these tests.

PANADO TABLETS with food, drink and alcohol

There is no significant effect on absorption of PANADO TABLETS when taken with meal.

Alcohol should be avoided when taking PANADO TABLETS.

Pregnancy, breastfeeding and fertility

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 healthcare provider for advice before taking this medicine.

Safety and efficacy in pregnancy and breastfeeding have not been established.

There is no available data on the effects of PANADO TABLETS on fertility.

Driving and using machines

PANADO TABLETS has no or negligible influence on the ability to drive and use machines.

It is not always possible to predict to what extent PANADO TABLETS may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which PANADO TABLETS affects you.

3. How to take PANADO TABLETS

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

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

Do not take more than the recommended dose.

The recommended doses are as follows:

Adults: One tablet every 3 hours or one to two tablets every 4 to 6 hours while symptoms persist. Do not take

more than 4 gram (8 tablets) in 24 hours.

Children 6 to 12 years: Half to one tablet while symptoms persist, to be repeated every 4 hours if needed to a maximum of 4 doses per 24 hours for not longer than 5 days. Do not give more than 2 gram (4 tablets) in 24 hours.

Do not give to children under 6 years of age (see section 2, 'Children and adolescents').

Do not take PANADO TABLETS for more than 10 days without consulting a doctor. If the pain persists or the fever lasts for more than 3 days or gets worse or other symptoms appear, you should stop the treatment and consult a doctor.

Method of administration

PANADO TABLETS should be taken orally.

The tablet should be swallowed with a glass of water.

If you take more PANADO TABLETS than you should

PANADO TABLETS contains paracetamol which may be fatal in overdose. In the event of overdose 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.

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

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

Abnormalities of glucose metabolism and metabolic acidosis may occur.

Cardiac dysrhythmias have been reported.

If you forget to take PANADO TABLETS

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

Instead you should simply continue with the next dose when it is due. Remember to leave at least four hours between doses.

4. Possible side effects

PANADO TABLETS can have side effects.

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

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

- swelling of the hands, feet, ankles, eyelids, face, tongue or lips
- decrease in blood pressure (hypotension)
- hives or welts (urticaria)
- shortness of breath (dyspnoea)
- severe dizziness
- difficulty in breathing
- mouth ulcers, cold sores and ulcers or soreness of your tongue
- skin lumps or hives (raised, red or white, itchy patches of skin)
- 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)
- serious skin reactions such as swelling, itching, red severe rash especially those covering your whole body (appearing as allergic wheals) (see section 2).

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

PATIENT INFORMATION LEAFLET

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

- nausea, vomiting, diarrhoea, upper stomach pain, stomach or intestinal bleeding, itching, loss of appetite
- dark urine, clay-coloured stools
- jaundice (yellowing of the skin or eyes).

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

Less frequent side effects

- bleeding problems or clotting disorders, decreased formation of cells, severe decrease in white blood cells which may lead to severe infections, frequent infections due to poorly functioning white blood cells or decrease in white blood cells, reduction in blood platelets, which increases the risk of bleeding or bruising, abnormal breakdown of red blood cells, which may cause weakness or pale skin, decrease in blood count, reduced neutrophil count in blood
- allergies (excluding swelling on the face, mouth, hands)
- low levels of glucose in the blood
- depression, confusion, sensing unreal things
- tremor, headache
- abnormal vision
- abnormal accumulation of fluid under the skin
- abnormal liver function, liver failure, death of liver cells (hepatic necrosis), liver damage
- sudden decrease in the amount of urine or cloudy urine
- blood in urine (haematuria)
- inability to urinate (enuresis)
- kidney disorders
- dizziness, generally feeling unwell (malaise), fever, drowsiness, interactions with medicines
- overdose and poisoning.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of PANADO TABLETS.

5. How to store PANADO TABLETS

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in a well-closed container protected from light.

Exposure to air should be kept to a minimum.

Do not store in a bathroom.

Do not take after the expiry date stated on the label.

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 PANADO TABLETS contains

- The active substance is paracetamol 500 mg.
- The other ingredients are maize starch, potassium sorbate (0,12 % *m/m*), magnesium stearate and colloidal silica.

What PANADO TABLETS looks like and contents of the pack

White to slightly off-white, round, biconvex tablets embossed with “PANADO” on one side and with break line and two indentations on the other side.

Polypaper strips of 2 tablets.

2 Polypaper strips of 2 tablets each in a carton.

PVC/Aluminium foil blister packs of 12 and 24 tablets.

PATIENT INFORMATION LEAFLET

White polypropylene tracer packs of 24 tablets.

White polypropylene securitainers of 10 and 20 tablets.

White HDPE Spartan containers of 24 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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