

Approved Patient Information Leaflet for Medicines for Human Use:

AUSTELL PARACETAMOL 500 mg tablets

SCHEDULING STATUS:

S0 All pack sizes smaller than 25 tablets.

S1 All pack sizes smaller than 25 tablets.

AUSTELL PARACETAMOL 500 mg tablets

Paracetamol

Sugar free

Read all of this leaflet carefully before you start taking AUSTELL PARACETAMOL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- AUSTELL PARACETAMOL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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

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

- Keep this leaflet. You may need to read it again.
- Do not share AUSTELL PARACETAMOL 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 7 days for adults and 3 days for children's.

What is in this leaflet

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

1. What AUSTELL PARACETAMOL is and what it is used for

AUSTELL PARACETAMOL contains paracetamol, is used for the relief of mild to moderate pain and fever such as headaches, toothache and pain associated with colds and flu, in adults and children older than 6 years.

2. What you need to know before you take AUSTELL PARACETAMOL

Do not take AUSTELL PARACETAMOL

- if you are hypersensitive (allergic) to paracetamol or any of the other ingredients of AUSTELL PARACETAMOL (listed in section 6).
- if you have any liver problem.

Warnings and precautions

Take special care with AUSTELL PARACETAMOL

Talk to your doctor or pharmacist before taking AUSTELL PARACETAMOL

- if you are suffering from liver or kidney disease.

Children and adolescents

Do not give to children aged under 6 years of age.

Other medicines and AUSTELL PARACETAMOL

Always tell your health care provider if you are taking any other medicine.

Talk to your doctor or a pharmacist if you are taking.

- Antibiotics (e.g. chloramphenicol), anti-sickness treatments (e.g. metoclopramide, domperidone), some treatments for diarrhoea caused by gall bladder disease, or lipid lowering drugs (cholestyramine), increases the uric acid level in urine (e.g. probenecid).
- Drugs that induce liver microsomal enzymes such as carbamazepine, phenytoin, phenobarbitone and rifampicin.
- Medicine that reduces the clotting of the blood (e.g warfarin).

AUSTELL PARACETAMOL with food and drinks

There is no known interaction of AUSTELL PARACETAMOL with food and drinks.

Pregnancy and breastfeeding

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 AUSTELL PARACETAMOL.

Driving and using machines

It is not always possible to predict to what extent AUSTELL PARACETAMOL 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 AUSTELL PARACETAMOL affects them.

3. How to take AUSTELL PARACETAMOL

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

Always take AUSTELL PARACETAMOL exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Adults: One to two tablets repeated every four to six hours as required. Do not take more than 8 tablets in 24 hours.

Children 6 – 12 years: Half to one tablet repeated every four to six hours as required. Do not take more than four tablets in 24 hours.

DO NOT EXCEED THE RECOMMENDED DOSE.

Method of administration

- You can take AUSTELL PARACETAMOL with meals, with beverages or independently of meals. If you have a sensitive stomach, you should best take AUSTELL PARACETAMOL after meals.
- Take the tablets with a sufficient quantity of liquid (e.g., one glass of water)
- Do not take with any other paracetamol-containing products.
- Do not give to children under 6 years of age.
- Do not exceed the stated dose.

If you take more AUSTELL PARACETAMOL than you should

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

If you forget to take AUSTELL PARACETAMOL

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

4. Possible side effects

AUSTELL PARACETAMOL can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are very serious side effects. If you have them, you may have had a serious reaction to AUSTELL PARACETAMOL. 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:

- difficulty breathing,
- signs of recurrent infections such as fever or sore throat,
- less urine than is normal for you,
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

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

Tell your doctor if you notice any of the following:

Less frequent side effects:

- loss of liver function causing yellowed skin and eyes (jaundice). along with stomach pain and swelling,
- unusual tiredness or weakness,
- pinpoint red spots on your skin,
- skin rash, hives or itching,
- sores, ulcers, or white spots on your lips or in your mouth,
- cloudy urine,
- blood disorders-changes in numbers and types of blood cells. Occasionally the blood does not clot well, which may result in easy bruising or bleeding,
- rarely, a severe reduction in the number of white blood cells, which makes infections more likely,
- bronchospasm (tight chest),
- inflammation of the pancreas (pancreatitis).

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 or pharmacist. 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 AUSTELL PARACETAMOL.

5. How to store AUSTELL PARACETAMOL

Store all medicines out of reach of children

- Store at or below 25 °C.
- Store in the original package.
- Protect from light.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label/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 AUSTELL PARACETAMOL contains

- The active substance is paracetamol.
- The other ingredients are *magnesium stearate, pregelatinised starch, purified water and sodium metabisulphite.*

What AUSTELL PARACETAMOL looks like and contents of the pack

AUSTELL PARACETAMOL is supplied in white opaque PVC/Aluminium blisters and packed into cardboard cartons in pack sizes of 1X10's, 2X10's and 1X20's.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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This leaflet was last revised in

05 December 2022

Registration numbers

36/2.8/0406

Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL:

<https://austell.co.za/product-info/>

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