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PATIENT INFORMATION LEAFLET

Scheduling Status
S1

PARACETAMOL GDC 500 mg tablets
Paracetamol
Contains sugar: powdered sucrose 20 mg / tablet

Read the entire leaflet carefully because it contains important information for you
PARACETAMOL GDC is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use PARACETAMOL GDC carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share PARACETAMOL GDC 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 PARACETAMOL GDC is and what it is used for
2. What you need to know before you take PARACETAMOL GDC
3. How to take PARACETAMOL GDC
4. Possible side effects
5. How to store PARACETAMOL GDC
6. Contents of the pack and other information

1. What PARACETAMOL GDC is and what it is used for
PARACETAMOL GDC belongs to a group of medicines known as analgesics and antipyretics.
This medicine is used for the relief of mild to moderate pain and fever.

2. What you need to know before you take PARACETAMOL GDC
Do not take PARACETAMOL GDC
- If you are sensitive (allergic) to paracetamol or ever had a harmful reaction to paracetamol or any of the other ingredients of PARACETAMOL GDC (listed in section 6).
- If you have severe liver function impairment.

Warnings and Precautions
Do not use continuously for more than 10 days without consulting your doctor.
Dosages in excess of those recommended may cause severe liver damage.
Patients suffering from liver or kidney disease should take paracetamol under medical supervision.
Consult your doctor if no relief is obtained with the recommended dosage.
If you are taking medicines on a regular basis, using this medicine at the same time with another medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

If you are pregnant or breastfeeding your baby while taking this medicine consult your doctor, pharmacist or other health care professional for advice.

Severe skin reactions have been reported in some patients taking paracetamol. If you develop any skin reactions stop taking PARACETAMOL GDC and consult your doctor or pharmacist or go to your nearest hospital.

Other medicines and PARACETAMOL GDC
Always tell your healthcare provider if you are taking any other medicine. This includes complementary or traditional medicines.

If PARACETAMOL GDC is taken at the same time as the medication listed below, unwanted side effects can be experienced:
- Hepatotoxic medicines (e.g. isoniazid): Increased risk of liver toxicity.
- Enzyme-inducing medicines (e.g. carbamazepine; rifampicin): Increased risk of liver toxicity and possible decreased effects of PARACETAMOL GDC.
- Metoclopramide (used for nausea and vomiting): Increased absorption of PARACETAMOL GDC.
- Probenecid (used to increase uric acid excretion): Decreased clearance and increased half-life of PARACETAMOL GDC.
- Cholestyramine (used to lower high cholesterol levels): Reduced absorption of PARACETAMOL GDC, if taken within one hour of cholestyramine.
- Salicylates (e.g. aspirin): Prolonged use can increase the risk of adverse kidney effects.
- Antibiotics (e.g. isoniazid – chronic use): Increased risk of liver damage.
- Antivirals: Paracetamol enhances the antiviral effect of interferon alfa.

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 healthcare provider for advice before taking this medicine.

Driving or using machines
It is not always possible to predict what effect PARACETAMOL GDC will have on you. Do not drive or use machines until you are aware of the effects it has on you.

PARACETAMOL GDC contains sugar (sucrose)
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take PARACETAMOL GDC
Always take PARACETAMOL GDC exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.
The usual doses are
- Children under 6 years: Not recommended.
- Children 6 - 12 years: Half to one tablet every 6 hours.
- Adults and Children over 12 years: One or two tablets every four to six hours, up to a maximum of eight (8) tablets daily.

If you take more PARACETAMOL GDC than you should
In the event of over dosage or suspected overdose and even if there are no symptoms, immediately consult your doctor or pharmacist. If neither is available, immediately rush the patient to the nearest hospital or poison control centre.

4. Possible side effects
PARACETAMOL GDC can have side effects.
Skin rashes and other allergic reactions may occur.
Leucopenia (decrease in leucocytes), neutropenia (decrease in neutrophils) and pancytopenia may occur.
Serious skin reactions (SCAR) which are potentially life threatening or fatal have been reported.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

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 "**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 PARACETAMOL GDC

5. How to store PARACETAMOL GDC
Store all medicines out of reach of children.
Store in a cool, dry place, in well closed containers below room temperature (25 ºC).
Protect from light.
Do not store in a bathroom.
Do not use after the expiry date stated on the label/carton or container.
Return all unused or expired medicines to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6. Content of pack and other information
The active substance is paracetamol 500 mg per tablet
The preservatives are:

Nipastat	0,097 % m/m
Benzoic acid	0,065 % m/m

The other ingredients are starch maize, powdered sucrose, Nipastat, spirit chloroform, gelatin, benzoic acid, magnesium stearate.

What PARACETAMOL GDC looks like and contents of the pack
A flat, round tablet with a breakline on one side.
Plastic bottle with a white cap containing 100, 500 and 1000 tablets.
Plastic bucket with a white lid containing 5 000 tablets.

Holder of the Certificate of Registration
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