PATIENT INFORMATION LEAFLET

VON PARACETAMOL 500 mg

Paracetamol

500 mg per tablet

SCHEDULING STATUS: S1

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

VON PARACETAMOL 500 mg (Tablets)

Read all of this leaflet carefully, before you start taking VON PARACETAMOL 500 mg, because it contains important information for you.

VON PARACETAMOL 500 mg is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use VON PARACETAMOL 500 mg carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share VON PARACETAMOL 500 mg 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 3 days of use.

WHAT VON PARACETAMOL 500 mg CONTAINS:

Each tablet contains 500 mg of paracetamol, as the active ingredient.

Preservatives: Nipastat 0,1 % *m/m*

Benzoic acid 0,06 % *m/m*

Other ingredients: Gelatin, maize starch, magnesium stearate, quinolene yellow (CI 47005), sodium metabisulphite, sodium starch glycolate and talc.

Sugar free

WHAT VON PARACETAMOL 500 mg IS USED FOR:

VON PARACETAMOL 500 mg belongs to a group of medicines known as analgesics and antipyretics.

VON PARACETAMOL 500 mg is used to relieve mild to moderate pain and fever, such as headaches, toothache and pain associated with colds and flu.

BEFORE YOU TAKE VON PARACETAMOL 500 mg:

Do not take VON PARACETAMOL 500 mg:

- If you are hypersensitive (allergic) to paracetamol of any of the other ingredients in VON PARACETAMOL 500 mg.
- If you have severe liver function problems.

Special caution should be taken with VON PARACETAMOL 500 mg:

- If pain or fever persists or gets worse at the recommended dosage of VON PARACETAMOL 500 mg, or if new symptoms occur.
- If you suffer from hepatitis (inflammatory condition of the liver).
- If you suffer from alcoholism.
- If you are recovering from any liver disease.
- If you have moderate kidney failure, or are on dialysis (treatment that performs functions of the kidneys).
- If you suffer with malnutrition (lack of sufficient nutrients in the body) or dehydration (significant loss of body fluids).

Pregnancy and breastfeeding:

VON PARACETAMOL 500 mg is generally considered safe for use in pregnant patients, if it is not used daily or on most days.

VON PARACETAMOL 500 mg is distributed into breastmilk, in small amounts that are not considered to be harmful to a breast-fed infant.

If you are pregnant or breastfeeding, please consult your doctor, pharmacist or other healthcare professional for advice before taking VON PARACETAMOL 500 mg.

Using other medicines with VON PARACETAMOL 500 mg:
If VON PARACETAMOL 500 mg 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 VON PARACETAMOL 500 mg.
- Metoclopramide (used for nausea and vomiting): Increased absorption of VON PARACETAMOL 500 mg.
- Probenecid (used to increase uric acid excretion): Decreased clearance and increased half-life of VON PARACETAMOL 500 mg.
- Cholestyramine (used to lower high cholesterol levels): Reduced absorption of VON PARACETAMOL 500 mg, 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.

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

HOW TO TAKE VON PARACETAMOL 500 mg:
Always take VON PARACETAMOL 500 mg as directed. You should check with your doctor or pharmacist if you are unsure.
Do not share medicines prescribed for you with any other person.
DO NOT EXCEED THE RECOMMENDED DOSE.

Children under 6 years:	Not recommended.
Children 6 – 12 years:	Half to one tablet (250 mg to 500 mg) every 6 hours. Not more than 4 doses to be taken in any 24-hour period.
Children over 12 years:	One tablet (500 mg) every 4 – 6 hours. Not more than 4 tablets (2000 mg) to be taken in any 24-hour period.
Adults:	One to two tablets (500 mg to 1000 mg) every 4 – 6 hours. Not more than 8 tablets (4000 mg) to be taken in any 24-hour period.

If you take more VON PARACETAMOL 500 mg than you should:
Symptoms of overdosage include paleness of the skin, nausea, vomiting, lethargy, sweating and pain in the abdominal area. Mild symptoms during the first 2 days of acute poisoning do not reflect the potential seriousness of the overdosage. Liver damage may become apparent 12 to 48 hours, or later, after ingestion.
Prompt treatment following overdosage is essential, even if you feel well.

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

If you missed a dose of VON PARACETAMOL 500 mg:
If you forget to take a dose, take it as soon as you remember, unless it is time for your next dose. In that case, take your next dose as normal.
Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS:
VON PARACETAMOL 500 mg can have side effects.
If any of the following happens, stop taking VON PARACETAMOL 500 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, face, lips, mouth or throat
- Difficulty breathing or swallowing
- Skin rash or itching

These are all very serious side effects, if you have them, you may have had a serious allergic reaction to VON PARACETAMOL 500 mg. 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:

- Blood test results that indicate a low white blood cell levels in the blood. Symptoms include a weak immune system that may make you more prone to infections.
- Low blood pressure, causing dizziness or fainting.

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

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

Not all side effects reported for VON PARACETAMOL 500 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

STORING AND DISPOSING OF VON PARACETAMOL 500 mg:
Store at or below 25 ˚C in a cool, dry place. Protect from light and moisture.
Keep containers and/or buckets tightly closed. Do not remove tablets from buckets or containers until required for use. Store VON PARACETAMOL 500 mg tablets in the original packaging. Do not use after the expiry date stated on the bucket or container.
Return all unused medicine to your pharmacist. Do not dispose of any medication in drains or sewerage systems (e.g. toilets).
STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF VON PARACETAMOL 500 mg:
Plastic buckets or containers (HDPE) of 1000 or 5000 tablets.

IDENTIFICATION OF VON PARACETAMOL 500 mg:
A round, flat, yellow tablet with a central score line on one side.

REGISTRATION NUMBER:
B/2.7/1480

NAME AND BUSINESS ADDRESS OF HOLDER OF CERTIFICATE OF REGISTRATION:
Gulf Drug Company (Pty) Ltd
22 Burnside Drive
Old Mill Industrial Park
Mount Edgecombe, 4300

DATE OF PUBLICATION OF PATIENT INFORMATION LEAFLET:
Date of the most recent amendment to the patient information leaflet as approved by the Authority: 25/06/2001
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