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## PATIENT INFORMATION LEAFLET

**Scheduling status** S1

# JP PARACETAMOL 500 mg (TABLETS)

**Paracetamol**
**Sugar free**

**Read the entire leaflet carefully because it contains important information for you**
JP PARACETAMOL 500 mg is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use JP PARACETAMOL 500 mg carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your health care provider or pharmacist if you need more information or advice.
- Do not share JP PARACETAMOL 500 mg with any other person.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

**What is in this leaflet**

1. What JP PARACETAMOL 500 mg is and what it is used for
2. What you need to know before you take JP PARACETAMOL 500 mg
3. How to take JP PARACETAMOL 500 mg
4. Possible side effects
5. How to store JP PARACETAMOL 500 mg
6. Contents of the pack and other information

### 1. What JP PARACETAMOL 500 mg is and what it is used for

JP PARACETAMOL 500 mg belongs to a group of medicines known as analgesics and antipyretics.
It is indicated for the relief of fever and mild to moderate pain such as headaches, toothache and pain related to colds and flu.

### 2. What you need to know before you take JP PARACETAMOL 500 mg

**Do not use JP Paracetamol 500 mg if:**

- you are sensitive (allergic) to paracetamol or any of the other ingredients of JP PARACETAMOL 500 mg listed in section 6
- you have severe liver function impairment.

**Warnings and precautions**
Use with caution if:

- you suffer from liver or kidney disease
- you need to use this medicine continuously – do not use for more than 10 days without consulting a doctor.

Ensure that you are well hydrated (drinking lots of water) when taking this medication.

Dosages greater than those recommended may cause damage to your liver. If you have liver or kidney disease this medicine should be used as directed by your doctor. Do not use continuously for more than 10 days without consulting your doctor. Using too much JP Paracetamol, or using it for long periods of time may be dangerous.

**Special precautions:**
1. Consult your doctor if you have no relief from the recommended dosage.
2. Store in a safe place out of reach of children.

**Other medicines and JP PARACETAMOL 500 mg**
**If you are taking medicines on a regular basis, including complementary and traditional medicines, using JP Paracetamol tablets at the same time with another medicine may cause undesirable interactions. Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)**

If JP 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 JP PARACETAMOL 500 mg.
- Metoclopramide (used for nausea and vomiting): Increased absorption of JP PARACETAMOL 500 mg.
- Probenecid (used to increase uric acid excretion): Decreased clearance and increased half-life of JP PARACETAMOL 500 mg.
- Cholestyramine (used to lower high cholesterol levels): Reduced absorption of JP 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.
- Antivirals: paracetamol enhances the antiviral effect of interferon alfa.

**Pregnancy and breastfeeding**
JP PARACETAMOL 500 mg has been used safely in pregnant and lactating women at the doses recommended.

**Driving or using machines**
It is not always possible to predict what effect JP PARACETAMOL 500 mg will have on you. Do not drive or use machines until you are aware of the effects it has on you.

**JP PARACETAMOL 500 mg contains sodium metabisulphites**
May rarely cause severe allergic (hypersensitivity) reactions and bronchospasm.

### 3. How to take JP PARACETAMOL 500 mg

**Do not share medicines prescribed for you with any other person.**
Always take JP PARACETAMOL 500 mg 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.
The usual dose is:
Adults: One or two tablets repeated every 3-4 hours if necessary, but not more than 8 tablets to be taken in any 24 hour period.
Children 6 to 12 years: Half to one tablet repeated every 3-4 hours if necessary, but not more than 4 doses in any 24 hour period.
Children under 6 years: Not recommended. Paracetamol syrup should rather be considered for use if such a medicine is necessary.

**If you have taken more JP PARACETAMOL 500 mg than you should**
Contact your doctor immediately, even if you feel well because of the risk of delayed and serious liver damage. **Prompt treatment is essential. In the event of overdosage, or suspected overdose and even if there are no symptoms, immediately consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison centre.**

**4. Possible side effects**

**The following side effects can occur with use of JP PARACETAMOL 500 mg**

Skin rashes and other allergic reactions may occur. The rash is usually red (erythematous) or raised and itchy (urticarial) but sometimes more serious and may be accompanied by fever and ulcers. Serious skin reactions (SCAR) which are potentially life threatening or fatal have been reported. JP PARACETAMOL 500 mg may cause changes in the make-up of the blood (neutropenia, pancytopenia and leucopenia), which causes symptoms such as unexplained bruising or bleeding, fatigue or fever.

Not all side effects reported for JP PARACETAMOL 500 mg are included in this leaflet. Should your general health worsen while taking JP PARACETAMOL 500 mg, 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 JP PARACETAMOL 500 mg.

**5. How to store JP PARACETAMOL 500 mg**

Store in a well-closed container protected from light. Store at or below 25°C. Exposure to air should be minimal.
Store all medicines out of reach of children.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
**Return all unused or expired medicines to your pharmacist.**

**6. Contents of the pack and other information**

**What JP PARACETAMOL 500 mg contains:**

The active substance is per tablet: paracetamol 500 mg.

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|---|---|---|
| Preservatives: | Nipastat | 0,1 % m/m |
| | Benzoic acid | 0,06 % m/m |

The other ingredients are starch maize, sodium starch glycolate, gelatine, Nipastat sodium, benzoic acid, sodium metabisulphite, purified talc, magnesium stearate, Deep Apple Green F1620 (CI 47005, 42090, 15985, 44090, 16255).

**What JP PARACETAMOL 500 mg looks like and contents of the pack**

Green, round, flat bevel edged tablet with a central break-line on one side packed in:

- White HDPE container of 100 and 1000 tablets.
- White polypropylene bucket containing 5000 tablets.

**Holder of the Certificate of Registration**

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