

FLAT DIMENSION = 160 x 430mm

FOLDED DIMENSION = 160 x 27mm

30 mm

10mm

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### PARACETAMOL 500mg CAPSULES Paracetamol

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

1. What Paracetamol Capsules are and what they are used for
2. What you need to know before you take Paracetamol Capsules
3. How to take Paracetamol Capsules
4. Possible side effects
5. How to Store Paracetamol Capsules
6. Contents of the pack and other information

#### 1. What Paracetamol Capsules are and what they are used for

Paracetamol is an analgesic and an antipyretic which means it relieves pain and lowers temperature. These capsules are used for the relief of:

- Fever, pain, headache, migraine, sharp nerve pain (neuralgia), toothache, sore throat, period pains, aches and pain.
- symptomatic relief of rheumatic aches and pains, influenza symptoms, feverishness and feverish colds.

#### 2. What you need to know before you take Paracetamol Capsules

##### Do not take these capsules if you:

- are allergic to paracetamol or any other ingredients (listed in section 6).

#### Warnings and precautions

**Take special care and talk to your doctor or pharmacist before taking Paracetamol Capsules if you:**

- are suffering from liver problems including liver problems due to excessive alcohol consumption
- are suffering from Gilbert's syndrome (mild jaundice)
- are suffering from kidney problems
- suffer from alcoholism
- are suffering from dehydration and chronic malnutrition
- suffer from asthma, particularly if your asthma is worsened by aspirin.
- are taking any other paracetamol containing medicines
- have a fever that does not improve after taking this medicine
- have glucose-6-phosphatedehydrogenase deficiency (enzyme deficiency)
- have haemolytic anemia (abnormal breakdown of red blood cells).

Caution should be exercised when taking paracetamol prior to (less than 72 hours before) or at the same time as intravenous busulfan.

During treatment with paracetamol, tell your doctor straight away if:

- you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

**This medicine contains paracetamol; do not take with any other paracetamol-containing products at the same time.**

#### Other medicines and Paracetamol Capsules

**Tell your doctor or pharmacist if you are taking or have recently taken any other medicine, even those not obtained without a prescription.**

The following medicines can affect Paracetamol:

- medicines used to treat bacterial infections (e.g. isoniazid used to treat tuberculosis)
- medicines used to treat epilepsy (fits) (e.g. lamotrigine, carbamazepine, phenobarbital, phenytoin, primidone)

- Metoclopramide, Domperidone (used to treat sickness and nausea)
- oral contraceptives ("The Pill", mini-pill), hormonal implants and HRT
- Warfarin and other coumarin medicines (used to thin blood) due to increased risk of bleeding
- Probenecid (Medicine used to treat high levels of uric acid in the blood stream (gout))
- diflunisal (an anti-inflammatory painkiller)
- Colestyramine 'used to treat high cholesterol' and in diseases of the intestine and liver
- Medicine to treat fever or mild pain (Aspirin, Salicylamide)
- Barbiturates and tricyclic antidepressants (to treat depression)
- intravenous busulfan (used in chemotherapy to treat cancer)
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2)

#### Effects of paracetamol on laboratory tests

Uric acid and blood sugar tests may be affected.

#### Paracetamol capsules with food and drink

This medicine may be taken with or without food.

#### Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If necessary, paracetamol can be used during pregnancy. You should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your doctor or midwife if the pain and/or fever are not reduced or if you need to take the medicine more often.

Small amounts of paracetamol may pass into breast milk.

This medicine may be taken, as instructed (see section 3), by mothers who are breast-feeding.

#### Driving and using machines

Paracetamol has no influence on the ability to drive and use machines.

#### Paracetamol Capsules contain Parahydroxybenzoates

- The capsule shell contains propyl parahydroxybenzoate (E216) and methyl parahydroxybenzoate (E218) which may cause allergic reactions (possibly delayed).

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10mm

SAME SIZEARTWORK  
430 mm x 160 mm

### Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially ‘sodium-free’.

### 3. How to take Paracetamol Capsules

- Always take this medicine exactly as advised by your doctor. Check with your doctor or pharmacist if you are not sure.
- Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor.
- The capsules should be swallowed whole with a drink of water.

#### Adults, the elderly and children of 16 years and over:

Take two capsules not more than every 4 hours as required, to a maximum of 8 capsules in a day.

#### Children aged 12 – 15 years:

Take one capsule every 4-6 hours when necessary to a maximum of 4 capsules in a day.

#### Children under 12 years:

Do not give to children under 12 years.

If symptoms persist see your doctor, do not take for more than 3 days unless you have been told to do so by your doctor.

#### If you take more Paracetamol capsules than you should

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

If you (or someone else) swallow a lot of capsules at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include feeling or being sick, loss of appetite, stomach pain or liver damage.

#### If you forget to take the Paracetamol Capsules

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

As can happen with any medicine, a few people may develop an allergic reaction. If you experience any of the following, stop taking this medicine immediately, and see your doctor or pharmacist:

- allergic reactions which may be severe such as skin rash, peeling of the skin, itching, swollen red areas of the skin, sometimes with shortness of breath or swelling of the mouth, lips, tongue, throat or face.
- shortness of breath, sudden wheezing, fluttering or tightness of the chest or collapse

Not known - A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

Side effects that have been reported with Paracetamol 500mg Capsules are:

- bruising more easily, sore throat or other signs of infection (these may be signs of a blood disorder)
- severe pain in the abdomen and back, with fever (high temperature), loss of appetite, nausea and vomiting (these may be signs of pancreas inflammation)
- worsening of asthma
- very rare cases of serious skin reactions have been reported.

#### Tell your doctor if you get any of these side effects:

- skin rash.

The use of this medicine over a long time can cause kidney problems. If you experience any side effects or feel that the medicine is affecting you badly tell your doctor or pharmacist immediately.

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

### 5. How to store Paracetamol Capsules

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Store in the original package.
- Do not use the capsules after the expiry date printed on the carton after (EXP). The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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

#### What Paracetamol capsules contain

- The active substance is Paracetamol.
- The other ingredients are: pregelatinised maize starch, magnesium stearate and sodium laurylsulfate.
- The capsule shell contains: titanium dioxide (E171), erythrosine (E127), quinolone yellow (E104), patent blue (E131), gelatin, methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216).

#### What Paracetamol capsules look like and contents of the pack

- They are red and white hard gelatine capsules, containing white free flowing powder.
- They are available in cartons containing 100 capsules.

#### Marketing Authorisation Holder and Manufacturer

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#### Paracetamol 500mg Capsules; PL 17907/0245

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