

## Patient Information Leaflet Paracetamol 250mg/5ml Oral Suspension

Read all of this leaflet carefully because it contains important information for you. This medicine is available without a prescription. However, you still need to use Paracetamol Oral Suspension carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if you or your child's symptoms worsen or do not improve after 3 days.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### In this leaflet

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### 1. What this medicine is for

Paracetamol belongs to a group of medicines called analgesics that help to ease pain.

It is used to treat mild to moderate pain and other conditions such as headaches, toothache, earache, sore throat, colds & influenza, aches and pains and to bring down fever (high temperature) including fever caused by immunisation.

### 2. Before using this medicine

This medicine is suitable for most people but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

#### **X Do not take or give this medicine if you/your child...**

- **has ever had** a bad reaction to any of the ingredients (see section 6).
- **is taking** anything else with paracetamol in it. Paracetamol is often included in cold and flu remedies, and in other medicines you can buy (such medicines have "contains paracetamol" printed on the pack).

If any of these apply, get advice from a pharmacist or doctor **without** using Paracetamol Oral Suspension.

#### **⚠ Talk to your doctor or pharmacist if you/your child:**

- has serious kidney or liver problems.
- are dependent on alcohol.
- has an inherited intolerance to some sugars.

#### **⚠ Taking other medicines:**

Tell your doctor or pharmacist if you or your child is taking any other medicines including herbal medicines and those you have bought yourself.

Paracetamol can interfere with the action of some other drugs and some drugs can have an effect on paracetamol. The drugs which can cause some problems when taken together with paracetamol are:

- cholestyramine (used in the treatment of high cholesterol levels)
- warfarin (used to thin the blood and prevent clotting)
- domperidone and metoclopramide (used in the treatment of nausea and vomiting)
- anticonvulsants (drugs to treat epilepsy).

#### **⚠ If adults take this medicine:**

The following additional warnings are included in case an adult takes this product:

- You can use this medicine while you are taking oral contraceptives ('the pill'), but it may not work as well on your pain or fever.
- If you drink large amounts of alcohol, you may be more open to the side effects of paracetamol.

#### **⚠ Pregnancy and Breast-feeding**

Ask your doctor or pharmacist for advice before taking this medicine if you are:

- pregnant or think you might be pregnant.
- breast-feeding.

If necessary Paracetamol Oral Suspension 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 if the pain and/or fever are not reduced or if you need to take the medicine more often.

#### **⚠ Driving and using machines**

This medicine is unlikely to affect your ability to drive or to operate machinery.

#### **⚠ Important information about some of the ingredients of Paracetamol Oral Suspension**

- Maltitol liquid: If you have been told by your doctor that you or your child have an intolerance to some sugars, contact your doctor before taking or giving your child this medicine.
- Sodium methyl parahydroxybenzoate (E219) and Sodium propyl parahydroxybenzoate (E217): May cause allergic reactions (possibly delayed).

### 3. How to take this medicine

Check the table below to see how much of the medicine to use.

- For oral use only.
- It is important to shake the bottle for at least 10 seconds before use.
- Do not give more medicine than the label tells you to. If your child does not get better, talk to your doctor.
- Do not give anything else containing paracetamol while giving this medicine.
- Do not overfill the spoon.

- Always use the spoon supplied with the pack. The big spoon measures 5ml and the small spoon measures 2.5ml.



Child's age	How much to give
6 - 8 years:	One 5ml spoonful (large end) four times a day.
8 - 10 years:	One 5ml spoonful (large end) and one 2.5ml spoonful (small end) four times a day.
10 - 12 years:	Two 5ml spoonfuls (large end) four times a day.
12 - 16 years:	Two - three 5ml spoonfuls (large end) up to four times a day.
Adults and children over 16 years:	Two - four 5ml spoonfuls (large end) up to four times a day.

- Do not give more than 4 doses in any 24 hour period
- Leave at least 4 hours between doses
- Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist
- Do not give to children under the age of 6 years.

If you are not sure of the cause of your child's illness or it is accompanied by a rash, breathing difficulties, diarrhoea or excessive tiredness or lethargy, speak to your doctor straight away. Do not give Paracetamol Oral Suspension until you get medical advice.

If you are worried, or not sure of when or how to use this medicine, ask your doctor or pharmacist for advice.

#### **⚠ If you give more Paracetamol Oral Suspension than you should**

If you accidentally take or give an overdose of this medicine, either call your doctor straight away, or go to your nearest hospital casualty department. Always take any remaining medicine, the container and the label with you, so that the medicine can be identified.

**Talk to a doctor at once if your child takes too much of this medicine even if they seem well. This is because too much paracetamol can cause delayed, serious liver damage.**

There may be no symptoms during the first 24 hours although loss of colour, feeling sick, vomiting and abdominal pain may occur.

#### **⚠ If you forget to give this medicine**

Give the next dose when needed provided that the last dose was given at least 4 hours ago. **Do not** give a double dose.

#### **4. Possible side effects**

Paracetamol Oral Suspension can have side effects, like all medicines, although these don't affect everyone and are usually mild.

If any of the following happen, **stop** giving Paracetamol Oral Suspension and tell your doctor immediately or go to the casualty department at your nearest hospital.

- allergic reactions including swelling of the face, tongue or throat, difficulty swallowing, unexplained wheezing, shortness of breath which may be accompanied by skin rash or hives.
- becoming unusually tired, unexpected bruising or bleeding and getting more infections (such as colds) than usual. These are very rare effects in people taking paracetamol.
- very rare cases of serious skin reactions have been reported. Symptoms may include: skin reddening, blisters, rash. If skin reactions occur or existing skin symptoms worsen, stop use and seek medical help right away.

If your child shows any of these signs, **stop giving paracetamol and talk to a doctor right away.**

#### **Long term use:**

People who use medicines containing paracetamol every day for a long time (several months or more) could get certain side effects, including liver and kidney damage.

People taking paracetamol in the usual way for shorter periods have not had these problems, but liver function tests may be affected.

#### **Reporting side effects**

If you or your child 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 at: [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. Storing your medicine**

- Keep out of the sight and reach of children.
- Do not store above 25°C. Keep the container in the outer carton. Discard after 2 months of first opening.
- Do not use Paracetamol Oral Suspension after the expiry date which is stated on the bottle after Exp.:. The expiry date refers to the last day of that month.
- Medicines should not be disposed via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### **6. Further information**

Each 5ml of suspension contains 250mg Paracetamol.

It also contains glycerol, polysorbate 80, xanthan gum (E415), maltitol liquid (E965), sodium saccharin (E954), citric acid monohydrate, sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), strawberry flavour (containing propylene glycol) and purified water.

Each bottle contains 100ml or 200ml of oral suspension.

The Marketing Authorisation for Paracetamol Oral Suspension (PL 20416/0522) is held by Crescent Pharma Limited, Units 3 & 4, Quidhampton Business Units, Polhampton Lane, Overton, Hampshire, RG25 3ED, UK.

It is manufactured by Crescent Manufacturing Ltd., 2 Cunard Road, Park Royal, London, NW10 6PN, UK.

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