

PACKAGE LEAFLET: INFORMATION FOR THE USER
Paracetamol 500mg/5ml Oral Solution
Paracetamol

Read all of this leaflet carefully before you start taking this medicine 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Paracetamol 500mg/5ml Oral Solution. It will be referred to as Paracetamol Oral Solution for ease hereafter.

What is in this leaflet:

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

1. WHAT PARACETAMOL ORAL SOLUTION IS AND WHAT IT IS USED FOR

Paracetamol Oral Solution contains paracetamol which is a pain-killer and also reduces a fever (high body temperature). This medicine is a higher strength Paracetamol Oral Solution. It is used for mild to moderate pain when you cannot take other paracetamol formulations such as lower strength liquid paracetamol, effervescent tablets or tablets.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PARACETAMOL ORAL SOLUTION

Do not take Paracetamol Oral Solution:

- if you are allergic to paracetamol or any of the other ingredients of this medicine (listed in section 6).
- if you have a liver disorder.

Warnings and precautions

Talk to your doctor or pharmacist before taking **Paracetamol Oral Solution:**

1. If you have liver disease, including those due to drinking too much of alcohol.
2. If you have kidney problems.
3. If you are taking or will be taking paracetamol.

During treatment with Paracetamol Oral Solution, tell your doctor straight away if:

- 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).

Do not take more than the recommended dose.

Children and adolescents

This medicine should not be given to children or adolescents under the age of 16 years.

Other medicines and Paracetamol Oral Solution

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines interact with each other and this can alter their effect. It is particularly important to tell your doctor or pharmacist if you are taking the following medicines:

- antidepressants, e.g. amitriptyline, imipramine
- barbiturates, e.g. phenobarbitone
- anticonvulsants, e.g. carbamazepine, sodium valproate
- metoclopramide (for feeling or being sick)
- domperidone (used to treat heart burn or for feeling or being sick)
- colestyramine (used to treat gall bladder problems and to lower the amount of fat in your blood)
- zidovudine (used in HIV infections and AIDS)
- anticoagulants which are used to prevent blood clotting, e.g. warfarin.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Some products which can be bought without a prescription may contain paracetamol, so always check the labels for ingredients.

Paracetamol Oral Solution with food, drink and alcohol

Do not drink alcohol whilst taking Paracetamol Oral Solution. This is because taking alcohol and paracetamol together can increase the risk of liver damage.

Pregnancy, breast-feeding and fertility

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

If necessary, Paracetamol Oral Solution 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.

Driving and using machines

There are no known effects on the ability to drive and use machines.

Paracetamol Oral Solution contains:

- glycerol which may cause headache, stomach upset and diarrhoea
- methyl parahydroxybenzoate and propyl parahydroxybenzoate which may cause allergic reactions (possible delayed)
- propylene glycol: this medicine contains 1530 mg propylene glycol in each 5ml. If you are pregnant or breast-feeding or suffer from a liver or kidney disease do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine .
- less than 1 mmol sodium (23 mg) per 5ml, that is to say essentially ‘sodium-free’.

3. HOW TO TAKE PARACETAMOL ORAL SOLUTION

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

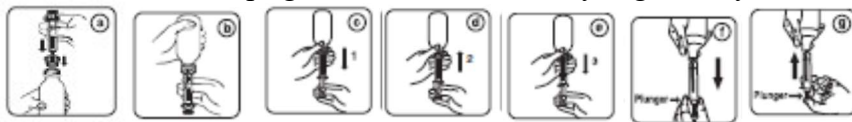
How to take

- this medicine contains 500mg of paracetamol in one 5ml dose
- take this medicine by mouth only
- shake the bottle for at least 10 seconds before use.

Make sure the tamper evident seal on the bottle is intact before use. Please use the oral syringe provided to deliver your specific dose (see instructions below). The syringe can be used to measure your dose by drawing the liquid to the correct mark on the syringe.

How to use the oral syringe:

1. Shake the bottle well, making sure the cap is firmly on the bottle.
 2. Remove the cap.
- Note: Keep the cap nearby to close the bottle after each use.
3. Push the plastic adapter into the neck of the bottle.
 4. Take the syringe and check the plunger is fully down.
 5. Keep the bottle upright and insert the oral syringe firmly into the plastic adapter.



6. Turn the whole bottle with the syringe upside down.
7. Slowly pull the plunger down fully so that the syringe fills with medicine. Push the plunger back up, to completely expel any large air bubble that may be trapped inside the oral syringe.
8. Then pull the plunger slowly back to the volume you need for your dose.
9. Turn the whole bottle with the syringe the right way up and take the syringe out of the bottle.
10. The dose of medicine can now be swallowed directly from the oral syringe. Please ensure that you are sitting upright and the plunger must be pushed slowly to allow you to swallow the dose. After administration remove the adaptor from the bottle, wash it and allow to dry till you use it the next time.
11. Replace the child proof cap after use.

12. Cleaning: After use, wipe the tip of the syringe with a dry, clean tissue.
Do not give this medicine with any other paracetamol containing product.
Do not exceed the stated dose.

The recommended dose is
Adults and young persons 16 years and over
500mg (5ml) to 1000mg (10ml) up to three to four times a day, as required. Maximum daily intake should not exceed 4g (40ml).

How often to take

- take a dose of this medicine every 4 to 6 hours when needed
- leave at least 4 hours between doses
- do not take more than 4 doses in 24 hours.

Check with your doctor about this.

Use in children and adolescents

Paracetamol Oral Solution is not recommended for children under 16 years.

If you take more Paracetamol Oral Solution than you should

You should not take more than 40ml of Paracetamol Oral Solution in 24 hours.

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.

Take the remaining solution and this leaflet with you so that the medical staff knows what you have taken.

There may be no symptoms during the first 24 hours although paleness, nausea (feeling sick), vomiting (being sick) and abdominal pain may occur.

If you forget to take Paracetamol Oral Solution

Do not take a double dose to make up for the forgotten dose. If you forget to take a dose then take your next dose at the usual time. Never take two doses at the same time.

4. POSSIBLE SIDE EFFECTS

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

Some side effects can be serious and you should tell your doctor immediately if you notice the following

- if you experience skin rash, flaking skin, boils, sore lips and mouth, swelling of the face, fever, sudden wheezing, fluttering or tightness of the chest or collapse
- bruising more easily, sore throat or other signs of infection. This could be because of a blood problem (such as blood dyscrasia including thrombocytopenia and agranulocytosis)
- if you experience severe pain in the abdomen and back, with fever (high temperature), loss of appetite, nausea and vomiting (these may be signs of pancreas inflammation).
- if paracetamol is taken for a long time; it may lead to liver and kidney problems
- a serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2) (Frequency “Not known”).

The following side effects have also been reported:

Very rare (may affect up to 1 in 10,000 people)

- very rare cases of serious skin reactions have been reported. These reactions can involve severe rash, blistering and / or redness which may be extensive involving the mucous membranes and large areas of the body.

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 at: 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 ORAL SOLUTION

- keep this medicine out of the sight and reach of children
- do not use this medicine after the expiry date which is stated on the bottle. The expiry date refers to the last day of that month
- keep this medicine in a dry place
- do not store above 25°C. Do not refrigerate or freeze
- keep the bottle in the outer carton in order to protect from light
- do not use 3 months after you first open it. Take it back to the pharmacy.
- 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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Paracetamol Oral Solution contains

- the active substance is paracetamol, 500mg in 5ml
- the other ingredients are citric acid monohydrate, erythrosine (E127), macrogol 400, glycerol, propylene glycol, methyl parahydroxybenzoate, propyl parahydroxybenzoate, raspberry flavor No.1, saccharin sodium, sodium citrate, purified water.

What Paracetamol Oral Solution looks like and contents of the pack

Paracetamol Oral Solution is a clear, pink thick liquid, with the smell of raspberry. It is available in an amber glass bottle with child proof cap packed in an outer box. A plastic dosing syringe (pipette) is also included to help measure the dose. Bottle sizes are 200ml and 300ml. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mercury Pharmaceuticals Ltd.,

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Manufactured By:

Kleva Pharmaceuticals SA
189 Parnithos Ave
13675 - Acharnai, Greece

This leaflet was last revised in January 2025.