1. What Paracetamol Oral Suspension is and what it is used for

Paracetamol Oral Suspension helps reduce mild to moderate pain, including:
- Headache
- Migraine
- Toothache
- Sore throat
- Period pains
- General aches and pains
- Minor aches and pains in the neck, shoulder or back
- Pain from a cold and flu
- Fever

2. What you need to know before you use Paracetamol Oral Suspension

Speak to your doctor or pharmacist before giving Paracetamol to a child:
- If s/he has an inherited intolerance to fructose or been diagnosed with an intolerance to some other sugars.
- If s/he has any other medicine that contains paracetamol.

Warnings and precautions

Speak to your doctor or pharmacist before giving Paracetamol to a child:
- If s/he has kidney problems
- If s/he has liver problems
- If s/he has an inherited intolerance to fructose or been diagnosed with an intolerance to some other sugars.

Your child may be more at risk of the side effects of paracetamol.

Speak to your doctor or pharmacist if any of these apply to your child.

3. How to use Paracetamol Oral Suspension

Take 2.5ml (1/2 teaspoon) for each 0.5 kg of body weight:

- 1.25ml (2 level teaspoons) for a child weighing 2.5 kg
- 2.5ml (1 teaspoon) for a child weighing 5 kg
- 5ml (2 teaspoons) for a child weighing 10 kg

Mix Paracetamol Suspension with water and give by mouth or use the double-ended measuring spoon provided. Do not use the 1.25ml graduation mark on the spoon for dosing.

4. Possible side effects

If you or your child get any of the following side effects, stop taking this medicine and see your doctor as soon as possible:
- 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
- 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 any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Paracetamol Oral Suspension

Keep out of the sight of and reach of children.
- Do not store above 25°C. Protect from light. Store in the original package.
- Do not use after the expiry date (month, year) on the label and carton. The expiry date refers to the last day of that month.
- If it is out of date or you no longer want it, take it back to the pharmacy.

6. Contents of the pack and other information

What Paracetamol Suspension contains

The active substance is paracetamol.

The other ingredients are methyl and propyl parahydroxybenzoate (E218 and E216), propylene glycol (E1520), xanthan gum (E415), liquid sorbitol (E420), sucrose, mango flavour, pineapple flavour (containing tartrazine (E102) and carmoisine (E122)), sweetness enhancer, sodium citrate and purified water.

Paracetamol belongs to a group of medicines called pain-killers or analgesics.
- It is used for mild to moderate pain including headache, migraine, nerve pain, toothache, sore throat, period pains and general aches and pains.
- It is also used to relieve the symptoms of cold and flu.
- It is also used to help reduce a fever (high temperature).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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.

If paracetamol is taken every day or for a long time (several months or more), it may lead to liver and kidney problems but if the right amount is taken over a short period of time there should be no problems, but liver function tests may be affected.

An allergic reaction may include:
- Skin rash, flaking skin, boils, sore lips and mouth, swelling of the face, fever.
- Sudden wheezing, fluffing or tightness of the chest or collapse.
- Sudden wheezing, fluffing of the chest or collapse.
- It may also be used to prevent complications from colds and flu.

It is used for mild to moderate pain including headache, migraine, nerve pain, toothache, sore throat, period pains and general aches and pains.

Paracetamol Suspension is a white to off-white liquid which smells of mango and pineapple.

Paracetamol Suspension comes in a brown glass bottle holding 100ml or 500ml of suspension. The pack contains a 2.5ml/5ml double-ended measuring spoon to measure the dose correctly (do NOT use the 1.25ml graduation mark on the spoon for dosing).
Other medicines and Paracetamol:
Tell your doctor if your child is taking any of these medicines:
■ barbiturates (sleeping tablets)
■ tricyclic antidepressants (such as amitriptyline)
■ colestyramine (used to treat high cholesterol)
■ warfarin (used to thin the blood and prevent clotting)
■ zidovudine (used in HIV infections and AIDS)
■ domperidone and metoclopramide (used to treat nausea and vomiting)
■ anticonvulsants (medicines used to treat epilepsy or fits)
■ fluoxetine (antidepressant), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment
■ if necessary Paracetamol can be used during pregnancy. You may be more susceptible to the side-effects of paracetamol. If this applies to you talk to a doctor before use.
■ if you are pregnant, planning to become pregnant or are breast-feeding, talk to your doctor or pharmacist before taking this medicine.
■ if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
■ this medicine should not affect your ability to drive or use machines.

### 3. How to use Paracetamol Oral Suspension

Use this medicine as your doctor or pharmacist has told you. Look on the label and ask your doctor or pharmacist if you are not sure.

**Using this medicine**

- **Check the table below to see how much medicine to use**
- **This medicine contains 250mg of paracetamol in one 5ml spoonful.**
- **Take this medicine by mouth only.**
- **Never give more medicine than shown in the table.**
- **It is important to shake the bottle for at least 10 seconds before use.**
- **Always use the spoon supplied with the pack. Do not overfill the spoon. Do not use the 12.5ml graduation marking on the spoon for dosing this product.**
- **Do not give this medicine with any other paracetamol-containing product.**

### How much to use

<table>
<thead>
<tr>
<th>Age</th>
<th>How Much</th>
<th>How often (in 24 hours)</th>
</tr>
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<tbody>
<tr>
<td>6 – 8 years</td>
<td>One 5.0 mL spoonful (large end)</td>
<td>4 times</td>
</tr>
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- **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 use more paracetamol than you should (overdose):
- **Immediate medical advice should be sought in the event of an overdose, even if you or your child seem well.** This is because too much paracetamol can cause delayed, serious liver damage. Phone your doctor or go to your nearest accident and emergency department straight away.
- **There may be no symptoms during the first 24 hours although paleness, nausea (feeling sick), sweating, vomiting (being sick), loss of appetite and abdominal pain may occur.**

If you forget to take this medicine:
Take the next dose when needed, provided that the last dose was taken at least 4 hours ago. Do not take a double dose to make up for a forgotten dose.

### 4. Possible side effects

Like all medicines, paracetamol can cause side effects, although not everybody gets them. The side effects below may sometimes happen.

If you or your child have an allergic reaction to this medicine see a doctor straight away.

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**ARTWORK**

**VERSION:** [Image 239x122 to 338x175]

**Print**

**Design Icon:** [Colour: BLACK 7474, PANTONE 995C, PANTONE 123C]

**Dimensions:** 210 x 300mm

**Name:** Steve

**Signs:**

**Date:**

**Third Party Approval**

**Name:**

**Signs:**

**Date:**

**Regulatory Approval**

**Name:**

**Signs:**

**Date:**
Other medicines and Paracetamol:
Tell your doctor if you or your child is taking any of these medicines:
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- tricyclic antidepressants (such as amitriptyline)
- colestyramine (used to treat high cholesterol)
- warfarin (used to thin the blood and prevent clotting)
- zidovudine (used in HIV infections and AIDS)
- domperidone and metoclopramide (used to treat nausea and vomiting)
- anticonvulsants (medicines used to treat epilepsy or fits)
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

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 so well on your pain or fever.
- if you drink large amounts of alcohol, talk to your doctor before you take this medicine. You may be more susceptible to the side-effects of paracetamol. If this applies to you, talk to a doctor before use.
- if you are pregnant, planning to become pregnant or are breast-feeding, talk to your doctor or pharmacist 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 if the pain and/or fever are not reduced or if you need to take the medicine more often.
- this medicine should not affect your ability to drive or use machines.

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

Paracetamol Suspension contains tartrazine and carmoisine, methyl and propyl parahydroxybenzoate, sorbitol. This medicine contains 682.0mg sorbitol per 5ml spoonful. Sorbitol is a source of fructose.

Propylene glycol. This medicine contains 163.9mg propylene glycol per 5ml spoonful. If you are person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

If you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, please tell your doctor or pharmacist before taking this medicine.

Use this medicine as your doctor or pharmacist has told you. Look on the label and ask your doctor or pharmacist if you are not sure.

Using this medicine

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If you use more paracetamol than you should (overdose):
- Immediate medical advice should be sought in the event of an overdose, even if you or your child seem well. This is because too much paracetamol can cause delayed, serious liver damage. Phone your doctor or go to your nearest accident and emergency department straight away.
- There may be no symptoms during the first 24 hours although paleness, nausea (feeling sick), sweating, vomiting (being sick), loss of appetite and abdominal pain may occur.

If you forget to take this medicine:
Take the next dose when needed, provided that the last dose was taken at least 4 hours ago. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, paracetamol can cause side effects, although not everybody gets them. The side effects below may sometimes happen.

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Continued overleaf
An allergic reaction may include:
- skin rash, flaking skin, boils, sore lips and mouth, swelling of the face, fever.
- sudden wheezing, fluttering or tightness of the chest or collapse.

If you or your child get any of the following side effects, stop taking this medicine and see your doctor as soon as possible:
- 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)
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5. How to store Paracetamol Oral Suspension
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- Do not use after the expiry date (month, year) on the label and carton. The expiry date refers to the last day of that month.
- If it is out of date or you no longer want it, take it back to the pharmacy.
- Do not use Paracetamol Suspension if you notice anything wrong with the medicine. Talk to your pharmacist.

6. Contents of the pack and other information
What Paracetamol Suspension contains
The active substance is paracetamol.

The other ingredients are methyl and propyl parahydroxybenzoate (E218 and E216), propylene glycol (E1520), xanthan gum (E415), liquid sorbitol (E420), sucrose, mango flavour, pineapple flavour (containing tartrazine (E102) and carmoisine (E122)), sweetness enhancer, sodium citrate and purified water.

Paracetamol Suspension is a white to off-white liquid which smells of mango and pineapple.

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The Marketing Authorisation Holder and Manufacturer is:
Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS1 1 9XE, UK.
Tel: + 44 (0) 113 244 1400

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