

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

- skin rash
- If paracetamol is taken for a long time, it may lead to liver and kidney problems. If any of the side effects gets serious, or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

**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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

**United Kingdom**

Yellow Card Scheme:  
[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.

**Ireland**

HPRA Pharmacovigilance  
 Earlsfort Terrace, IRL - Dublin 2  
 Tel: +353 1 6764971  
 Fax: +353 1 6762517  
 Website: [www.hpra.ie](http://www.hpra.ie)  
 e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

**5. How to store Paracetamol Oral Suspension**

- Keep out of the sight and reach of children.
- Do not store above 25°C. Do not refrigerate or freeze. Store in the original package.
- Do not use 1 month after you first open it. Take it back to the pharmacy.
- Do not use after the expiry date (month, year) on the label. 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- If it is out of date or you no longer want it, take it back to the pharmacy.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 Oral Suspension if you notice anything wrong with the medicine. Talk to your pharmacist.

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

**What Paracetamol Oral Suspension contains**

The active substance is paracetamol. Each 5ml contains 500mg paracetamol. The other ingredients are methyl and propyl parahydroxybenzoate (E218 and E216), propylene glycol (E1520), liquid maltitol (E965), saccharin sodium, acesulfame potassium (E950), sodium dihydrogen phosphate dihydrate, disodium hydrogen phosphate dihydrate, magnesium aluminium silicate, masking flavour, strawberry flavour and purified water.

**What Paracetamol Oral Suspension looks like and contents of the pack**

Paracetamol Oral Suspension is a pink-brown liquid which smells of strawberry. It comes in a brown glass bottle holding 150ml of oral suspension with a 5ml purple syringe and an adaptor

**The Marketing Authorisation Holder and Manufacturer is**

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK. Tel: + 44 (0) 113 244 1400

**This medicinal product is authorised in the Member States of the EEA under the following names:**

UK: Paracetamol Adult 500mg/5ml Oral Suspension  
 Ireland: Paracetamol Adult 500mg/5ml Oral Suspension

**This leaflet was last revised in 09/2018**

**Paracetamol Adult 500mg/5ml Oral Suspension**

**Read all of this leaflet carefully before you start taking this medicine.**



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

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

Paracetamol belongs to a group of medicines called pain-killers or analgesics. This medicine is a higher strength Paracetamol Oral Suspension. 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 Suspension**

**Do not take this medicine if you have:**

- had an allergic reaction to paracetamol or any of the ingredients listed in section 6. An allergic reaction can include a rash, itching or shortness of breath
- a liver disorder.

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

Do not take paracetamol if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking paracetamol.

**Warning and precautions**

Talk to your doctor or pharmacist before taking this medicine if you:

- have kidney problems
- have liver problems, including those due to drinking too much alcohol
- suffer from a condition known as Gilberts syndrome
- are taking other medicines that affect the liver
- suffer from glucose-6-phosphate dehydrogenase deficiency (enzyme deficiency)
- suffer from haemolytic anaemia (a reduction in the red blood cells which can make the skin pale yellow and cause weakness or breathlessness)
- suffer from reduced glutathione levels
- are malnourished, dehydrated or weigh less than 50 kg
- are elderly.

You may be more at risk of the side effects of paracetamol. Speak to your doctor or pharmacist if any of these apply to you.

*Continued overleaf*

G2AD1RBJ1

		<b>JOB INFORMATION</b> Product Name: Paracetamol 500mg/5ml Oral Suspension Strength: 500mg/5ml    New Item Code: G2AD1RBJ1 Pack Size: 150ml    Previous Item Code: P0765 Bottle Size: 150ml    Supplier Code: N/A Design Icon: N/A    Change Control No.: 927222		<b>JOB SPECIFICATION</b> Keyline Ref: UKL412    Pharmacode: 419 Dimensions: 210 x 300mm    EAN Code: N/A Folded Size: 30 x 150mm    No. of Colours: 1 Tabbed: NO    Page Number: 1 of 2		<b>APPROVALS</b> Third Party Approval Required    TICK APPLICABLE BOX    YES <input type="checkbox"/> NO <input type="checkbox"/> Name: _____ Signature: _____    Date: ____/____/____ Authority Approval Supplied    TICK APPLICABLE BOX    YES <input type="checkbox"/> N/A <input type="checkbox"/> Regulatory Sign-off Name: _____ Signature: _____    Date: ____/____/____	
<b>ARTWORK VERSION:</b> 3 Date: 12/09/18 Operator: NH		<b>PREFLIGHT VERSION:</b> - Date: - Operator: -		<b>MAIN BODY TEXT</b> Font Type: Univers Roman    Font Size: 10pt Univers Bold		Print Colours: BLACK <input type="checkbox"/> Non-print Colours: KEYLINE <input type="checkbox"/>	

Medicines containing paracetamol should only be used for a few days without advice from your doctor or dentist.

If you have a high fever, signs of a secondary infection or if symptoms persist for more than three days, consult your doctor.

Prolonged use of paracetamol, especially in combination with other pain killing medicinal products, may cause kidney problems.

**Other medicines and Paracetamol**

You must not take **any other medicines that contain paracetamol** while you are taking this medicine.

Tell your doctor if you are 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)
- chloramphenicol (used to treat infections).

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

**Paracetamol Oral Suspension with food and drink**

Do not drink alcohol while taking paracetamol. This is because taking alcohol and paracetamol together can increase the risk of liver damage.

**Pregnancy and breast-feeding**

If you are pregnant, planning to become pregnant or are breast-feeding, talk to your doctor or pharmacist before taking this medicine.

**Driving and using machines**

This medicine should not affect your ability to drive or use machines.

**Paracetamol Oral Suspension contains methyl and propyl parahydroxybenzoate and liquid maltitol**

Paracetamol Oral Suspension contains:

- Methyl and propyl parahydroxybenzoates – some people are allergic to these (the allergy may happen some time after starting the medicine).
- Liquid maltitol (2.05g per 5ml dose). If your doctor has told you that you cannot tolerate some sugars, talk to your doctor before taking this medicine.

**3. How to take Paracetamol Oral Suspension**

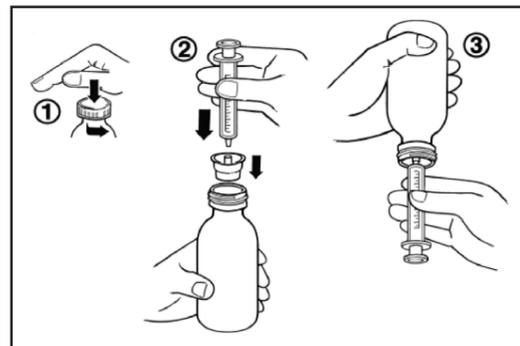
Take this medicine as your doctor or pharmacist has told you. Look on the label and ask your doctor or pharmacist if you are not sure.

**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.
- Always use the syringe supplied with the pack.

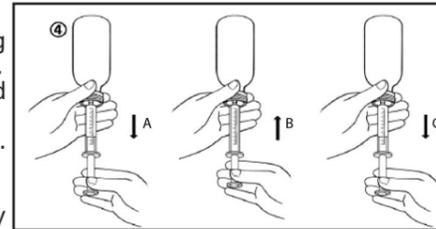
**Measuring your dose:**

1. Open the bottle: press the cap and turn it anticlockwise (figure 1).
2. Insert the syringe adaptor into the bottle neck (figure 2).
3. Take the syringe and put it in the adaptor opening (figure 2).
4. Turn the bottle upside down (figure 3).



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5. Fill the syringe with a small amount of solution by pulling the piston down (figure 4 A). Then push the piston upward in order to remove any possible bubbles (figure 4 B). Finally, pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 4 C).



6. Turn the bottle the right way up.
7. Remove the syringe from the adaptor. Put the end of the syringe into your mouth and push the piston slowly back in to take the medicine.
8. Wash the syringe with water and let it dry before you use it again.
9. Close the bottle with the plastic screw cap.

**How much to take**

- **Adults and adolescents over 16:** 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.
- Do not take more than 4 doses in 24 hours.

Do not exceed the stated dose.

**If you take more paracetamol than you should (overdose):**

- Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of 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), vomiting (being sick) and abdominal pain may occur.

**If you forget to take this medicine:**

Take the next dose when needed. 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 have an allergic reaction to this medicine see a doctor straight away.**

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 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)
- very rare cases of serious skin reactions have been reported.

Continued overleaf



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ARTWORK VERSION: **3**  
Date: 12/09/18  
Operator: NH

PREFLIGHT VERSION: -  
Date: -  
Operator: -

JOB INFORMATION	
Product Name:	Paracetamol 500mg/5ml Oral Suspension
Strength:	500mg/5ml
Pack Size:	150ml
Bottle Size:	150ml
Design Icon:	N/A
New Item Code:	G2AD1RBJ1
Previous Item Code:	P0765
Supplier Code:	N/A
Change Control No.:	927222

Print Colours: BLACK

JOB SPECIFICATION	
Keyline Ref:	UKL412
Dimensions:	210 x 300mm
Folded Size:	30 x 150mm
Tabbed:	NO
Pharmacode:	419
EAN Code:	N/A
No. of Colours:	1
Page Number:	2 of 2
MAIN BODY TEXT	
Font Type:	Univers Roman
Font Size:	10pt
Font Type:	Univers Bold
Non-print Colours:	KEYLINE

APPROVALS	
Third Party Approval Required	TICK APPLICABLE BOX YES <input type="checkbox"/> NO <input type="checkbox"/>
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Authority Approval Supplied	TICK APPLICABLE BOX YES <input type="checkbox"/> N/A <input type="checkbox"/>
Regulatory Sign-off	
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