



ORBIT PHARMACEUTICALS

DRUG PRODUCT REGISTRATION DOSSIER

Product Name	ORPAR-125
Generic Name	Paracetamol Pediatric Oral Suspension B.P.

1.3.2 Patient Information Leaflet

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 give Paracetamol Oral Suspension to a child
3. How to use 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.

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).

2. What you need to know before you give Paracetamol Oral Suspension to a child Do not give Paracetamol to a child:

If s/he is allergic to paracetamol or any of the other ingredients of this medicine An allergic reaction can include a rash, itching or shortness of breath

If s/he is taking anything else with paracetamol in it

If s/he is between 2-3 months old and is taking this medicine for other causes of pain and fever and:

- weighs less than 4 kg or
- was born before 37 weeks.

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

Warnings and precautions

Talk to your doctor or pharmacist before giving Paracetamol to a child:

If s/he has kidney problems

If s/he has liver problems



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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.

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).

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 have liver problems, including those due to drinking too much alcohol, you may be more open 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.

3. How to use Paracetamol Oral Suspension

Always give 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 tables below to see how much medicine to use

This medicine contains 125 mg of paracetamol in one 5 ml spoonful.

Take this medicine by mouth only.



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It is important to shake the bottle for at least 10 seconds before use.

Always use the Measuring cap supplied with the pack. Do not overfill the Measuring cap.

Do not give this medicine with any other paracetamol-containing product.

Age	Avg.Wt	Dose	Age	Avg.Wt	Dose
6 Months	6.4 Kg	4 ml	5 Years	18 Kg	11 ml
1 Year	9 Kg	6 ml	7 Years	21 Kg	13 ml
2 Years	12 Kg	8 ml	10 Years	30 Kg	18 ml
3 Years	15 Kg	9 ml	12 Years	36 Kg	22 ml

If you give more paracetamol than you should (overdose):

Immediate medical advice should be sought in the event of an overdose, even if your child seems well. This is because too much paracetamol can cause delayed, serious liver damage.

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 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 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 your child has 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 your child gets any of the following side effects, stop giving 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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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 paracetamol is taken 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.

5. How to store Paracetamol Pediatric Oral Suspension

Keep out of the sight 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.

6. Contents of the pack and other information

What Paracetamol Suspension contains

The active substance is paracetamol.

The other ingredients are Acrysol, Glycerin, Sucrose (Sugar granulated), Sodium benzoate, Sodium methacrylate, Sodium Propyl paraben, Sodium saccharin, Aspartum, Sodium Metabisulphate, Di sodium EDTA, Carmoisine, Citric acid monohydrate, Purified Water

What Paracetamol Suspension looks like and contents of the pack

Paracetamol Suspension is a Pink colour Suspension

It comes in a Amber colour pet bottle ,packed in carton is provided to measure the dose of measuring cylinder and packing insert.



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1.3.3 Container Labels

Attached