This medicine brings down high temperatures (also called fever) and relieves pain. It is normally given to babies over 2 months and children up to 10 years.

Do not give it to children on this list:

- Not to babies or children taking other medicines, see section 2.
- Not to anyone who is allergic to the ingredients. See section 6.
- Follow the dosage instructions carefully. Children of different ages need different amounts. These are shown in the tables. See section 5.
- If a child is not getting better, or needs more medicine than shown in the table. See section 5.
- If a child gets a rash, breathing problems, diarrhoea or gets very tired. See section 2.

New read this whole leaflet carefully before you use this medicine. Nearly all the medicines you buy are prescription-only medicines, but in the case of this product means that this product is unsuitable for adults to take.

1 What the medicine is for

The preparation in CALPOL® Infant Oral Suspension is used to relieve pain and/or bring down fever (high temperature) in many conditions including:

- Post-immunisation fever, teething, headache, cold and flu, sore throat, earache, toothache, post-operational pain, post-inflammation pain, headache, rheumatic pain, muscle and joint pain.
- Oral Suspension is used to relieve pain and/or bring down fever (high temperature) in many conditions including;

2 Before giving the medicine to your child

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.

Do not give your child this medicine:

- If the child has ever had a bad reaction to any of the ingredients.
- If the child is allergic to aspirin or any of the ingredients.
- If the child is taking anything else with paracetamol in it.
- If the child is under 2 months old and not taking the medicine for other causes of pain and fever and:

3 Do not give more medicine than the label tells you to.

If any of these apply, show the bottle or pack to your pharmacist. If any of these bullet points apply, contact your doctor or pharmacist. If you are not sure about the medicine your child is taking, show the bottle or pack to your pharmacist.

If any of these bullet points apply, talk to a doctor or pharmacist.

4 Adults

Take this medicine:

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

- You can use the medicine while you are taking and combine the (the drug), if it may not work as well or may cause side effects.
- If you drink large amounts of alcohol, you may be more open to the side effects of paracetamol. If this applies to you, talk to a doctor before use.

- If necessary, the medicine can be used during pregnancy. You should use the lowest possible dose that relieves your pain and/or fever and use it for the shortest time possible. Contact your doctor or pharmacist if the pain and/or fever are not reduced or if you need to take the medicine more often.

5 Some of the ingredients can cause problems

- If a child has serious kidney or liver problems.
- If your child has an inherited intolerance to lactose or your child is diagnosed with an intolerance to some sugars. See section 3.
- If your child is taking any other medicines including:
- If your child is taking any other medicines including:
- If your child is taking any other medicines including:

6 If your child is taking any other medicines including:

7 Notice the size of the signs:

- If your child is taking any other medicines including:

- If your child is taking any other medicines including:

8 Turn over

This medicine contains 2.2 g of sucrose per 5 ml dose which is equivalent to 50 mg/kg. This should be taken into account in patients with diabetes mellitus.

Sorbitol is a source of fructose. If your doctor has told you that your child has an intolerance to some sugars or if your child has been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your pharmacist or doctor before using this medicine. For babies and children who are allergic to one ingredient, the medicine can be used if the other ingredients are tolerated.

9 How to use this medicine

Check the table to see which medicine to use.

For each use only.

■ Always use the medicine supplied with the pack.

■ Always take the medicine once the bottle helps you. If your child does not get better, talk to your doctor.

■ Do not give anything else containing paracetamol while giving this medicine.

10 How to use the syringe

Place the syringe pump or the plunger down on the plunger to either 2.5 or 5 ml as recommended (see tables for the correct dose).

■ Turn the bottle the right way up.

■ Remove the syringe by holding onto the bottle and twisting off gently.

■ Place the syringe inside the child’s mouth against the cheek and press the plunger firmly. Do not hold the plunger in position.

■ After use, the syringe and the plunger should run off the bottle. If necessary, take the child to see your doctor immediately. This means that this medicine is unsuitable for adults to take.

■ This medicine contains 2.2 g of sucrose per 5 ml dose and 451 mg of sorbitol (E420) per 5 ml dose which is equivalent to 50 mg/kg. This should be taken into account in patients with diabetes mellitus.

■ Sorbitol is a source of fructose. If your doctor has told you that your child has an intolerance to some sugars or if your child has been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your pharmacist or doctor before using this medicine. For babies and children who are allergic to one ingredient, the medicine can be used if the other ingredients are tolerated.

■ This medicine contains 2.2 g of sucrose per 5 ml dose which is equivalent to 50 mg/kg. This should be taken into account in patients with diabetes mellitus.
Children over 6 years
Ask a pharmacist to recommend a suitable product.

Speak to your doctor:
- If your baby needs more than the doses shown in the table, or if their fever doesn’t go away, speak to your doctor as soon as possible.
- 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 CALPOL® until you get medical advice.

If anyone has too much
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.

If you forget to give the 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.

Possible side-effects
CALPOL® Infant Original 120mg/5ml Oral Suspension can have side-effects, like all medicines, although these don’t affect everyone and are usually mild.

Tell your doctor as soon as possible if you notice any of these:
- allergic reactions including swelling of the face, tongue or throat, difficulty swallowing, unexplained wheezing, shortness of breath, 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.

If you notice any side-effects not included in this leaflet please tell your doctor or pharmacist.

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: 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 this medicine
Keep this medicine out of the sight and reach of children. Do not store above 25°C. Keep bottle in the outer carton. Do not use after the end of the month shown as an expiry date on the packaging. 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 protect the environment.

6 Further information
What’s in this medicine?
The active ingredient is: Paracetamol 120 mg per 5 ml.
Other ingredients are: Sucrose, sorbitol liquid (E420), glycerol, polysorbate 80, aspartame potassium, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), ethyl parahydroxybenzoate (E214), microcrystalline cellulose and carmellose sodium, xanthan gum and purified water. The flavouring is strawberry (containing propylene glycol (E1520)) and colouring is carmoisine (E122). Each 5 ml of this product contains 2.2 g of sucrose.

The medicine looks like
CALPOL® Infant Original 120mg/5ml Oral Suspension is a pink oral liquid, available in 100 ml and 200 ml bottles. It contains 120 mg of the active ingredient Paracetamol in every 5 ml of medicine.

The Marketing Authorisation holder is McNeil Products Limited, S0 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.
The manufacturer is Delpharm Orleans, 5 avenue de Concor, 45271 Orleans, Cedex 2, France.
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