

Package leaflet: Information for the user



Read all of this leaflet carefully before you start using this medicine because it contains important information for you. Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If your child gets any side-effects, talk to your doctor or pharmacist. This includes any possible side-effects not listed in this leaflet. See section 4.
- You must talk to a doctor if your child does not feel better or feels worse after 3 days.

What is in this leaflet

1. What Calpol® is and what it is used for
2. What you need to know before you use Calpol®
3. How to use Calpol®
4. Possible side-effects
5. How to store Calpol®
6. Contents of the pack and other information

1 What Calpol® is and what it is used for

The paracetamol in Calpol® 120 mg/5ml Sugar Free Infant Oral Suspension is used to relieve pain such as tooth pain, headache, sore throat and aches and pains that come with colds and flu. It also brings down fever (high temperature).

2 What you need to know before you use Calpol®

Do not give your child this medicine...

- If s/he has ever had a bad reaction to paracetamol or any of the other ingredients in this medicine (see section 6).
- If s/he is taking anything else with paracetamol in it.
- If s/he weighs less than 4 kg.

If any of these apply, get advice from a doctor or pharmacist without using Calpol®

Warnings and precautions

Talk to your doctor or pharmacist...

- If your child has serious kidney or liver problems.
- If your child has an inherited intolerance to fructose or been diagnosed with an intolerance to some other sugars.
- If your child has Gilbert's syndrome (familial non-haemolytic jaundice).
- If your child has a condition called Glucose-6-phosphate dehydrogenase deficiency.
- If your child has haemolytic anaemia.
- If your child has glutathione deficiency.
- If your child is dehydrated or chronically malnourished.

During treatment with Calpol® 120 mg/5ml Sugar Free Infant Oral Suspension, tell your doctor straight away if:

- If your child has severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or your child suffers 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).

Other medicines and Calpol®

Tell your doctor or pharmacist if you or your child is taking any other medicines including:

- *metoclopramide* or *domperidone* (used to treat nausea and vomiting)

- *cholestyramine* (used to treat high cholesterol)
 - *anticoagulants* (drugs that thin the blood, such as warfarin)
 - *anticonvulsants* (drugs to treat epilepsy)
 - *flucloxacillin* (an antibiotic) due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).
 - medicines that can affect liver function.
- 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.

If adults take this medicine:

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, you may be more open to the side-effects of paracetamol.
- If necessary, the medicine 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 pharmacist if the pain and/or fever are not reduced or if you need to take the medicine more often.
- If you are breastfeeding, ask your doctor or pharmacist for advice before taking this medicine.
- If you weigh less than 50 kg, ask your doctor or pharmacist for advice before taking this medicine.
- If you are elderly and are frail or immobile or you have kidney or liver problems, you should ask your doctor or pharmacist for advice before taking this product, as you may need to take a reduced dose.

Calpol® contains methyl, propyl and ethyl parahydroxybenzoate, maltitol liquid, sorbitol and carmoisine.

- Methyl (E218), propyl (E216) and ethyl (E214) par hydroxybenzoate may cause allergic reactions which could possibly be delayed.

- This medicine contains 700 mg sorbitol liquid in each 5 ml which is equivalent to 140 mg/ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you (or your child) 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. Sorbitol may cause gastrointestinal discomfort and have a mild laxative effect.

- This product contains maltitol liquid (E965). If you have been told by your doctor that you (or your child) have an intolerance to some sugars, contact your doctor before you or your child takes this medicine. Maltitol has a calorific value of 2.3 kcal/g. Maltitol may have a mild laxative effect.
- Carmoisine (E122) may cause allergic reactions.

- This medicine contains less than 1mmol sodium (23mg) per 5ml, that is to say essentially 'sodium-free'.

- This medicine contains 14.32 mg propylene glycol (E1520) in each 5ml dose, which is equivalent to 2.86 mg/ml.

- This medicine contains 0.16mg benzyl alcohol in each 5ml which is equivalent to 0.03mg/ml. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you (or your child) are pregnant or breastfeeding, or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can buildup in your (or your child's) body and may cause side effects (called "metabolic acidosis").

- This medicine contains 0.00071mg of alcohol (ethanol) in each 5ml which is equivalent to 0.000142 mg/ml. The amount in 5 ml is equivalent to less than 1ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

3 How to use Calpol®

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Check the tables below to see how much medicine to use.

- For oral use only

- Always use the syringe supplied with the pack.

- Do not overfill the syringe

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

- Never give more medicine than shown in the table

- Do not overfill the spoon.

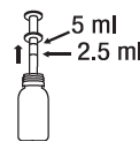
- Always use the spoon supplied with the pack.

- Do not give with any other paracetamol-containing products

- If preferable, you may dispense the contents of the syringe into a spoon before administering it to your child.



How to use syringe



Shake the bottle for at least 10 seconds and remove the cap.

- There is a plug with a hole in the neck of the bottle. Insert the end of the syringe into the hole and ensure it is secure.

- Hold the syringe in place and turn the bottle upside down and gently pull down the plunger to either 2.5 ml or 5 ml as appropriate (see tables for the correct dose).

- Turn the bottle the right way up.

- Remove the syringe by holding onto the bottle and twisting out gently.

- Ensure your child is supported in an upright position before administering the dose via the syringe.

- Carefully place the tip of the syringe into the child's mouth.

- Point the tip of the syringe towards the inside of the cheek.

- Ensure the medicine is released at the front of the mouth and not towards the back of the throat.

- Press the plunger gently to release a trickle. Do not squirt it out quickly.

- The child should be allowed time to swallow the medicine.

- After use, the plug should remain in the neck of the bottle. Wipe the plug and neck clean and rinse and dry the cap before replacing.

- The syringe should be washed and air dried after use. It should be cleaned by hand without removing the plunger.

Babies under 2 months

Do not give to babies under 2 months old. Consult your doctor.

Babies 2 – 3 months

Child's age - 2-3 months	How much
1. Post-vaccination fever	2.5 ml
2. Other causes of pain and fever - if your baby weighs over 4 kg and was born after 37 weeks	If necessary, after 4-6 hours, give a second 2.5 ml dose.
■ Do not give to babies less than 2 months of age. ■ Do not give more than 2 doses unless your doctor or nurse has advised otherwise. ■ Leave at least 4 hours between doses. ■ If further doses are needed, talk to your doctor or pharmacist.	

Children from 3 months to 6 years

Child's age	How much - up to 4 times a day
3-6 months	2.5 ml
6-24 months	5 ml
2-4 years	7.5 ml (5 ml + 2.5 ml)
4-6 years	10 ml (5 ml + 5 ml)
■ 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.	

Children over 6 years

Ask a pharmacist to recommend a suitable product.

Speak to your doctor:

■ If your child needs more than the doses shown in the table, or if 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

Immediate medical advice should be sought in the event of an overdose, even if the child seems well, because of the risk of delayed, serious liver damage.

If you forget to give Calpol®

Give the next dose when needed, provided that the last dose was given at least 4 hours ago. Do not give a double dose.

4 Possible side-effects

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

Stop using this medicine and contact your doctor immediately if you experience:

■ Severe skin reactions. Symptoms may include, skin reddening, blisters, rash.

Tell your doctor as soon as possible if you notice any of these:

■ allergic reactions including unexplained wheezing, shortness of breath, passing out or swelling of face and throat.

■ skin rashes or other signs of allergy.

■ 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 and are due to changes in blood cells.

■ A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2). This side effect has a frequency of "not known" which means it cannot be estimated from the available data).

If your child shows any of these signs, stop giving paracetamol and talk to a doctor.

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.

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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side-effects you can help provide more information on the safety of this medicine.

5 How to store Calpol®

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Store in the original container.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Calpol® contains

The active substance is paracetamol. Each 5 ml of oral suspension contains 120 mg paracetamol.

The other ingredients are: Maltitol liquid (E965), glycerol, polysorbate 80, Sorbitol liquid (E420) methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), ethyl parahydroxybenzoate (E214), dispersible cellulose, xanthan gum and purified water. The flavouring is strawberry (containing propylene glycol (E1520), benzyl alcohol, and ethanol) and colouring is carmoisine (E122).

What Calpol® looks like and contents of the pack

CALPOL® Infant Oral Suspension is a pink oral liquid, available in 60 ml, 70 ml, 100 ml and 140 ml bottles. Not all pack sizes may be marketed. A 5 ml graduated measuring syringe is provided.

Marketing Authorisation Holder and Manufacturer.

The Marketing Authorisation holder is JNTL Consumer Health I (Ireland) Ltd, Block 5, Hight Street, Tallaght, Dublin 24, Ireland.

The manufacturer is Delpharm Orleans, 5 avenue de Concyr, 45071 Orléans, Cedex 2, France.

This leaflet was last revised in

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