

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 take 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/5 ml 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 applies, **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.

⚠ Other medicines and Calpol®

Tell your doctor or pharmacist if 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)
- 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, sorbitol and carmoisine.

- Methyl (E218), propyl (E216) and ethyl (E214) parahydroxybenzoate may cause allergic reactions which could possibly be delayed.
- This medicine contains 700 mg sorbitol 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 caloric value of 2.3 kcal/g. Maltitol may have a mild laxative effect.
- Carmoisine (E122) may cause allergic reactions.

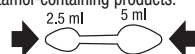
3 How to use Calpol®

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
- Each sachet contains 5 ml of this medicine.
- Any unused contents of the open sachet should be discarded.
- Never give more medicine than shown in the table.
- Do not overfill the spoon.
- Always use the spoon supplied with the pack.
- It is important to **massage the sachet** before use.
- Do not give with any other paracetamol-containing products.

There is a double-ended spoon in the pack.



👶 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.
<ul style="list-style-type: none"> ■ 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. 	

3 How to use Calpol® (continued)

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 baby 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 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.

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.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@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 (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 medicines you no longer use. These measures will help to protect the environment.

6 Contents of the pack and other information

What Calpol® contains

The active substance is: Calpol Sugar Free Infant Oral Suspension contains 120 mg Paracetamol in each 5 ml

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 and colouring is carmoisine (E122).

See section 2.

What Calpol® looks like and contents of the pack

CALPOL® Sugar Free Infant Oral Suspension is a pink oral liquid, available in 60 ml and 140 ml bottles and packs of 12 x 5 ml sachets. A spoon with a 2.5 ml and 5 ml measure is supplied with all packs of the product.

Marketing Authorisation Holder and Manufacturer

The Product Authorisation holder is Johnson & Johnson (Ireland) Ltd., Airton Road, Tallaght, Dublin 24, Ireland.

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

This leaflet was last revised in September 2019.

CALPOL® is a registered trade mark.

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