

Package leaflet: Information for the user



120 mg/5 ml

Infant Oral Suspension Contains Paracetamol

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 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 is allergic to paracetamol or any of the other ingredients of this medicine (listed in 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.

⚠ 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)
- colestyramine (used to treat high cholesterol)
- anticoagulants (drugs that thin the blood, such as warfarin)
- anticonvulsants (drugs to treat epilepsy)

If you are not sure about the medicine your child is taking, show the bottle or pack to your pharmacist.

Immediate medical advice should be sought in the event of an overdose, even if the patient feels well because of the risk of irreversible liver damage.

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 you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Calpol contains methyl, propyl and ethyl parahydroxybenzoate, sucrose, sorbitol and carmoisine.

- Methyl (E218), propyl (E216) and ethyl (E214) parahydroxybenzoate may cause allergic reactions which could possibly be delayed.
- The sucrose and sorbitol (E420) content of this product means that it may be unsuitable for some people. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This medicine contains 2.2 g of sucrose per 5 ml. This should be taken into account in patients with diabetes mellitus.
- Carmoisine (E122) may cause allergic type reactions.

3 How to use Calpol

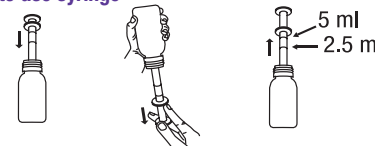
Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

- For oral use only.
- Always use the syringe supplied with the pack.
- Do not overfill the syringe
- It is important to shake the bottle thoroughly for at least 10 seconds before use.
- Never give more medicine than shown in the tables below.
- Do not give this medicine with any other paracetamol-containing product.
- If preferable, you may dispense the contents of the syringe into a spoon before administering it to your child.



i 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 5ml 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 dried after use. It can be cleaned by hand or in a dishwasher.

turn over ►

3 How to use Calpol (continued)

i Babies under 2 months

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

i Babies 2 - 3 months

Child's age - 2-3 months	How much
1. Post-vaccination fever	2.5 ml If necessary, after 4-6 hours, give a second 2.5 ml dose.
2. Other causes of pain and fever - if your baby weighs over 4 kg and was born after 37 weeks	2.5 ml

- Do not give to babies less than 2 months of age.
- Do not give more than 2 doses.
- Leave at least 4 hours between doses.
- If further doses are needed, talk to your doctor or pharmacist.

i 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.

i 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 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.

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.

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 HPRRA 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: Paracetamol 120 mg per 5 ml.

The other ingredients are: Sucrose (sugar), Sorbitol liquid (E420) liquid, glycerol, polysorbate 80, Acesulfame Potassium, 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).

Each 5 ml of this product contains 2.2 g of sucrose and 0.45 g of sorbitol.

What Calpol looks like and contents of the pack

Calpol Infant Oral Suspension is a pink oral liquid, available in 60 ml and 140 ml bottles. It contains 120 mg of the active ingredient Paracetamol in every 5 ml of medicine.

Marketing Authorisation Holder and Manufacturer

The Product Authorisation holder is McNeil Healthcare (Ireland) Ltd., Airtown Road, Tallaght, Dublin 24, Ireland.

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

This leaflet was last revised October 2014.

Calpol is a registered trade mark.

McNeil
Healthcare (Ireland) Ltd.

F310263
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Orleans - Artworks Center

CALPOL Infant Suspension 60-140 ml	IE
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Component number	Component type	Dimensions	Client	Version
F310263	Notice bobine / Rolled Leaflet	160 x 210 mm	J&J	v10.2
Safety code	Technical specification	Main font type	Minimum font size	
DATAMATRIX	NOTC010	-	-	

Colours			
Recto 1	Verso 1	Recto 2	Verso 2
PMS 527	PMS 527		
BLACK	BLACK		

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