

Package Leaflet: Information for the User

CALPOL* Sugar Free Infant Suspension

Paracetamol 120 mg/5 ml Oral Suspension

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been recommended for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same.
- 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.

What is in this leaflet:

- 1 What Calpol Sugar Free Infant Suspension is and what it is used for
- 2 What you need to know before you use Calpol Sugar Free Infant Suspension
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1 What Calpol Sugar Free Infant Suspension is and what it is used for

Calpol Sugar Free Infant Suspension contains 120mg paracetamol (the active ingredient) in each 5ml dose. There are also some inactive ingredients in Calpol Sugar Free Infant Suspension.

Calpol Sugar Free Infant Suspension is used for the relief of mild to moderate pain including teething pains and headache. It is also used to lower a high temperature (fever). For severe pain, a very high temperature, or if the medicine does not appear to be easing the symptoms, consult your doctor.

2 What you need to know before you use Calpol Sugar Free Infant Suspension

Do not give Calpol Sugar Free Infant Suspension:

- If your child is allergic (hypersensitive) to paracetamol or any of the other ingredient of Calpol Sugar Free Infant Suspension (listed in Section 6).

Warnings and precautions

- Talk to your doctor or pharmacist before using Calpol Sugar Free Infant Suspension if your child:
 - suffers from severe kidney or liver disease.
 - is underweight or malnourished.

- has inherited intolerance to fructose or you have been told that you have an intolerance to some sugars.
- is taking warfarin or similar medicines used to thin the blood.

You may need to avoid giving this product to your child altogether or limit the amount of paracetamol that your child takes.

- Check with your doctor before use if your child:
 - has a severe infection as this may increase the risk of metabolic acidosis.

Signs of metabolic acidosis include:

- deep, rapid, difficult breathing
- feeling sick (nausea), being sick (vomiting)
- loss of appetite

Contact a doctor immediately if you get a combination of these symptoms.

- Contains paracetamol. Taking too much paracetamol can cause serious harm to your child's liver. Do not give your child any other products that contain paracetamol whilst they are taking Calpol Sugar Free Infant Suspension, if you are unsure, ask your doctor or pharmacist.
- Calpol Sugar Free Infant Suspension may be used at the same time as drugs for epilepsy but when taken with some epileptic drugs the pain or fever may not be reduced as much. The use of certain antidepressants, sedatives, drugs for epilepsy or too much alcohol may cause the person taking this medicine to be more likely to suffer from the side effects of paracetamol. If you are unsure about other drugs that are being taken, ask your doctor or pharmacist.

Sorbitol: This medicine contains 0.525 mg sorbitol in each 5 mL which is equivalent to 0.105 mg/mL.

Maltitol: If your child has been told by your doctor that they have an intolerance to some sugars, contact your doctor before giving them this medicinal product.

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

Propylene glycol: This medicine contains less than 1 mg propylene glycol per 5 mL of oral solution which is equivalent to less than 1 mg/kg/day. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

This medicine contains carmoisine which may cause allergic reactions.

This medicine contains methyl parahydroxybenzoate and propyl parahydroxybenzoate which may cause allergic reactions (possibly be delayed).

3 How to use Calpol Sugar Free Infant Suspension

If you have any difficulties or do not understand the instructions ask your doctor or pharmacist.

Ensure the medicine is given as your doctor/pharmacist has told you. The label on it will usually tell you how much to give and how often. If you are not sure ask your doctor or pharmacist.

Always use the lowest effective dose to relieve your child's symptoms.

Do not exceed the stated dose.

Age : 2 – 3 months	Dose
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	
<ul style="list-style-type: none">• 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.	

Children aged 3 months - 6 years:

Child's Age	How Much	How often (in 24 hours)
3 – 6 months	2.5 ml	4 times
6 – 24 months	5 ml	4 times
2 – 4 years	7.5 ml (5 ml + 2.5 ml)	4 times
4 – 6 years	10 ml (5 ml + 5 ml)	4 times
<ul style="list-style-type: none">• 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 aged 6 to 12 years: Calpol Sugar Free Infant Suspension is not recommended for children within this age range. Ask your doctor or pharmacist to recommend a suitable alternative.

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

If you give more Calpol Sugar Free Infant Suspension than you should

It is important that the amount recommended by your doctor/pharmacist as shown above, is taken.

If your child accidentally swallows too much Calpol Sugar Free Infant Suspension, tell your doctor straight away, even if your child does not have any symptoms because there is a risk of delayed, serious liver failure which can lead to liver transplant or death. If you cannot see your doctor, go straight to the accident and emergency unit of your nearest hospital. Take the medicine with you to help the hospital staff identify what has been taken.

If you forget to give Calpol Sugar Free Infant Suspension

If a dose is forgotten, do not worry; give the next dose if necessary. Just remember, no more than four doses should be taken in a day.

4 Possible side effects

Most people taking this medicine find that it causes no problems. As with all medicines a few people may find that it causes side effects.

Stop using Calpol Sugar Free Infant Suspension and tell your doctor immediately if:

- Your child experiences allergic reactions with any of the following symptoms soon after taking Calpol Sugar Free Infant Suspension: skin rashes or peeling or mouth ulcers, sometimes with breathing problems or swelling of the face, tongue and/or throat, difficulty swallowing.
- Your child is unusually tired, develops unexpected bruising or bleeding and getting more infections (such as colds) than usual. These reactions are rare.
- Your child has previously experienced breathing problems with aspirin or non-steroidal anti-inflammatory medicines, and experienced a similar reaction with this product. These reactions are rare.

Long term use of paracetamol preparations may result in liver and/or kidney damage.

Some people who take medicines containing paracetamol for more than a couple of months may also have other side effects. Alcoholics who take medicines containing paracetamol in addition to alcohol may also suffer severe side effects. These effects include liver and kidney damage. However, people who take the recommended dose for shorter lengths of time have not experienced these problems.

If any other symptoms are experienced that you do not understand, tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Calpol Sugar Free Infant Suspension

- Do not use after the date shown as “Exp” on the carton and label.
- Keep your Calpol Sugar Free Infant Suspension where children cannot see or reach it. It may harm them.
- Store at room temperature (below 25 °C) in its original bottle and away from direct light and heat.
- Do not throw away 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 Contents of the pack and other information

What Calpol Sugar Free Infant Suspension contains

- The active ingredient is paracetamol 120 mg/5ml oral suspension.
- The other ingredients are maltitol solution, sorbitol solution, glycerol, dispersible cellulose, xanthan gum, methyl hydroxybenzoate, propyl hydroxybenzoate, strawberry flavour (contains propylene glycol), carmoisine (contains sodium) and purified water.

What Calpol Sugar Free Infant Suspension looks like and contents of the pack

Within each carton is a glass bottle with a child-resistant cap, which contains 140 ml of oral solution.

Marketing Authorisation Holder and Manufacturer

GlaxoSmithKline (Ireland) Ltd, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland hold the product licence.

Calpol Sugar Free Infant Suspension is made by Aspen Bad Oldesloe GmbH, Industriestrasse 32-36, D-23843 Bad Oldesloe, Germany.

If you have any questions or are not sure about anything, ask your doctor or pharmacist who will advise you.

This product can be dispensed without a medical prescription as recommended by your pharmacist.

Product name: Calpol Sugar Free Infant Suspension

MA number: MA192/03703

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