SCHEDULING STATUS:

S0 : 50 ml, 60 ml, 100 ml

S1 : 150 ml, 200 ml

Calpol Orange Paediatric Suspension (1 ml contains 24 mg of paracetamol)

Contains sugar.

Alcohol free.

Read all of this leaflet carefully because it contains important information for you.

Calpol Orange Paediatric Suspension is available without prescription for you to treat mild illness. Nevertheless, you still need to use Calpol Orange Paediatric Suspension carefully to get the best results:

- 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, pharmacist or nurse. 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 if your child feels worse after 3 days.
- The leaflet is written in terms of giving this medicine to your child, but if you are an adult who is intending to take this medicine yourself the information in this leaflet will apply to you as well.

What is in this leaflet

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

1. What Calpol Orange Paediatric Suspension is and what is it used for

Each 5 ml of Calpol Orange Paediatric Suspension contains 120 mg of paracetamol.

Paracetamol reduces pain and fever.

Calpol Orange Suspension is indicated in children aged 1 month to 12 years.

Calpol Orange Suspension is used for the treatment of mild to moderate pain and treatment of fever.

2. What you need to know before you use Calpol Orange Paediatric Suspension

Do not give Calpol Orange Paediatric Suspension:

- If your child is allergic to the active substance or to any of the excipients listed in Section 6.

Warnings and special precautions

Talk to your doctor, pharmacist or nurse before using Calpol Orange Paediatric Suspension

- This product contains paracetamol. Do not use more than the recommended dose as it may cause serious harm to the liver
- Do not give this medicine if your child is using any other prescription or non-prescription medicines containing paracetamol to treat pain, fever, symptoms of cold and flu, or to aid sleep
- Always read and follow the label

Check with your doctor before use if your child:

- has liver or kidney problems

- is underweight or malnourished

You may need to avoid using this product altogether or limit the amount of paracetamol that you use.

Check with your doctor before use if your child:

- has a severe infection, is severely malnourished or severely underweight 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 your child gets a combination of these symptoms.

Please see your doctor if symptoms do not improve.

Keep out of sight and reach of children.

Children

Do not give to infants less than one month of age.

Other medicines and Calpol Orange Paediatric Suspension

Tell your doctor or pharmacist if your child is using or has recently used or might use any other medicines.

Before giving this medicine, make sure you consult your doctor if your child is using warfarin or similar medicines used to thin the blood.

Calpol Orange Suspension contains

Each 24 mg/ml of paracetamol (120 mg/5 ml) suspension contains sorbitol (E 420) at 750 mg per 5 ml suspension. Sorbitol (E 420) and maltitol (E 965) are 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) use or receive this medicine.

Methyl parahydroxybenzoate (E 218) and Propyl parahydroxybenzoate (E 216) may cause allergic reactions (possibly delayed).

3. How to use Calpol Orange Paediatric Suspension

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

Check with your doctor, pharmacist or nurse if you are not sure.

Do not use more than 60 mg/kg (to be administered in divided doses of 10-15 mg/kg throughout the 24-hour period).

Minimum dosing interval: 4 hours.

No more than four doses in any 24-hour period.

Not recommended in children under 1 month. Do not use for more than 3 days without asking your doctor.

For children under 3 months: If fever persists for more than 24 hours (4 doses) seek medical advice. This is to ensure that fever that may be due to a serious infection is quickly diagnosed.

Please see a doctor if symptoms do not improve.

Dosing Table for 24 mg/ml (120 mg/5 ml) Oral suspension:

24 mg/mL		
Average Weight	**Age**	**mL**
4 kg	1 M	2 mL
5-6 kg	2-3 M	3 mL
7-9 kg	4-12 M	4 mL
10-12 kg	13-24 M	6 mL
13-15 kg	2-3 Y	8 mL
16-19 kg	4-5 Y	10 mL
20-25 kg	6-7 Y	12 mL
26-31 kg	8-9 Y	16 mL
32-42 kg	10-12 Y	20 mL

M = month Y = year

Do not use more than the recommended dose as it may cause serious harm to the liver.

Use the smallest dose that your child needs to treat his symptoms and use the medicine for the shortest period of time necessary.

If you use more Calpol Orange Paediatric Suspension than you should

seek medical advice from a doctor immediately even if your child does not have any symptoms because of the risk of liver failure.

If you forget to use Calpol Orange Paediatric Suspension

Do not use a double dose to make up for a forgotten dose.

4. Possible side effects

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

Stop using this medicine and tell your doctor immediately if your child:

- experiences allergic reactions such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face
- experiences a skin rash or peeling, or mouth ulcers
- has experienced breathing problems with aspirin or non-steroidal anti-inflammatories, and experiences a similar reaction with this product
- experiences unexplained bruising or bleeding

These reactions are very rare.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of Calpol. By reporting side effects, you can help provide more information on the safety of Calpol.

5. How to store Calpol Orange Paediatric Suspension

Store at or below 30 °C.

Do not use this medicine after the expiry date which is stated on the carton and bottle label. 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 protect the environment.

KEEP OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What Calpol Orange Paediatric Suspension contains

- The active substance is paracetamol.

  Each 5 ml of suspension contains 120 mg paracetamol.
- The other ingredients are:

  Sorbitol (70 % liquid) non-crytallising), xanthan gum, methyl parahydroxybenzoate, propyl parahydroxybenzoate, citric acid anhydrous, tri-sodium citrate dihydrate, glycerin, orange flavor, disodium EDTA, sucralose, maltitol syrup.

What Calpol Orange Paediatric Suspension looks like and contents of the pack

Calpol Orange Suspension is an opaque white suspension.

The product is provided in glass bottles which is packed into a carton. The pack sizes are 50 ml, 60 ml, 100 ml, 150 ml and 200 ml. Not all pack sizes may be marketed.

7. Name and business address of manufacturer

Haleon South Africa (Pty) Ltd

11 Hawkins Avenue

Epping Industria 1

Cape Town,

7460

Date of publication of this patient information leaflet

Date of the most recently revised professional information as approved by council: 24 June 2025

8. Registration Number

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