Infant
Sugar Free
Colour Free
120 mg/5 ml
Oral Suspension
Paracetamol

- This medicine brings down high temperatures (also called fever) and relieves pain.
- The medicine is OK for most babies over 2 months and children up to 6 years.
- **Do not give it to children on this list:**
  - Not to babies or children taking some other medicines. *See section 2* ▸
  - Not to anyone who is allergic to the ingredients. *See section 6* ▸
- **Follow the dosage instructions carefully.** Children of different ages need different amounts. These are shown in the tables. *See section 3* ▸
- **Speak to your doctor** if anything in this list applies:
  - If a child is not getting better, or needs more medicine than shown in the table. *See section 3* ▸
  - If a child gets a rash, breathing problems, diarrhoea or gets very tired. *See section 3* ▸

Now read this whole leaflet carefully before you use this medicine. Keep the leaflet: you might need it again.

1 What the medicine is for

The paracetamol in CALPOL® Infant Sugar Free Colour Free 120 mg/5 ml Oral Suspension is used to relieve pain and / or bring down fever (high temperature) in many conditions including post-immunisation fever, teething, headache, cold and flu, toothache, earache, sore throat and other aches and pains.

2 Before giving the medicine to your child

This medicine is suitable for most people but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

Do not give your child this medicine…

- **If s/he has ever had a bad reaction** to any of the ingredients.
- **If s/he is taking anything else with paracetamol in it.**
- **If s/he is between 2-3 months old** and is taking this medicine **for other causes of pain and fever and:**
  - Weighs less than 4 kg **or**
  - Was born before 37 weeks

If any of these applies, **get advice from a pharmacist or doctor without using CALPOL®.**

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 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.

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.
- Ask your doctor or pharmacist for advice before taking this medicine if you might be pregnant or breast-feeding.

Some of the ingredients can cause problems

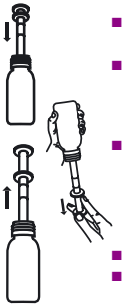
- Methyl (E218), propyl (E216) and ethyl (E214) parahydroxybenzoate may cause allergic reactions which could possibly be delayed.
- The sorbitol liquid (E420) and maltitol liquid (E965) content of this product means that this product is unsuitable for people with inherited intolerence to fructose.
- Maltitol liquid may have a mild laxative effect. It has a calorific value of 2.3 kcal/g.

3 How to use this medicine

Check the tables to see how much medicine to use.

- For oral use only.
- Always use the syringe supplied with the pack.
- Do not give more medicine than the label tells you to. If your child does not get better, talk to your doctor.
- Do not give anything else containing paracetamol while giving this medicine.

How to use the 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 in to 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.
- Place the syringe inside the child's mouth against the cheek and press the plunger slowly to gently release the medicine.
- After use, the plug should remain in the neck of the bottle. Wipe the plug and neck clean and rinse the cap before replacing.
- The syringe should be washed and dried after use. It can be cleaned by hand or in a dishwasher.

Babies under 2 months

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

Babies 2 - 3 months

For the relief of fever after vaccinations at 2, 3 and 4 months - 2.5 ml. This dose may be given up to 4 times a day starting at the time of vaccination. Do not give more than 4 doses in any 24 hour period. Leave at least 4 hours between doses. If your baby still needs this medicine two days after receiving the vaccine talk to your doctor or pharmacist.
Pain and other causes of fever - refer to the tables below.

turn over ▸

(continued)

Child's age	How Much
2-3 months	**2.5 ml** If necessary, after 4-6 hours, give a second 2.5 ml dose.

- Do not give to babies less than 2 months of age.
- Only give if your baby weighs over 4 kg and was born after 37 weeks.
- Leave at least 4 hours between doses.
- Do not give more than 2 doses. This is to ensure that fever that may be due to a serious infection is quickly diagnosed. If your child is still feverish after two doses, talk to your doctor or pharmacist.

Children from 3 months to 6 years

Child's age	How much	How often (in 24 hours)
3-6 months	2.5 ml	Up to 4 times
6-24 months	5 ml	Up to 4 times
2-4 years	7.5 ml (5 ml + 2.5 ml)	Up to 4 times
4-6 years	10 ml (5 ml + 5 ml)	Up to 4 times

- 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.

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

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

Talk to a doctor at once if your child takes too much of this medicine, even if they seem well. This is because too much paracetamol can cause 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

CALPOL® Infant Sugar Free Colour Free 120 mg/5 ml Oral Suspension can have side-effects, like all medicines, although these don't affect everyone and are usually mild.

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

- allergic reactions including swelling of the face, tongue or throat, difficulty swallowing, unexplained wheezing, shortness of breath which may be accompanied by skin rash or hives.
- 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.
- very rare cases of serious skin reactions have been reported. Symptoms may include: skin reddening, blisters, rash. If skin reactions occur or existing skin symptoms worsen, stop use and seek medical help right away.

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

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, but liver function tests may be affected.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

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

5 Storing this medicine

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

Do not store above 25°C.

Keep bottle in the outer carton.

Do not use after the end of the month shown as an expiry date on the packaging.

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.

6 Further information

What's in this medicine?

The active ingredient is: Paracetamol 120 mg per 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.

What the medicine looks like

CALPOL® Infant Sugar Free Colour Free 120 mg/5 ml Oral Suspension is an off-white liquid, available in 100 ml bottles. It contains 120 mg of the active ingredient paracetamol in every 5 ml of medicine.

The Marketing Authorisation holder is McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.

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

This leaflet was revised December 2016.

CALPOL® is a registered trade mark.

McNeil Products Ltd.

LN509601
16-0382

Orleans - Artworks Center

Client	JNJ
Change request #	CRD 1138
Product	CALPOL INFANT CF-SF SUSPENSION 100ML UK
Component #	LN509601
Old component #	F310513
ATW version	6.3
Component type	Rolled Leaflet
Dimensions	160 x 210 mm
Drawing #	NOTC010
Safety code type & #	Datamatrix LN509601
Client code	16-0382
Main font type	Helvetica Neue LT Std 57 Condensed
Minimum font size	7.5 pts

Colours

Recto 1		Verso 1		Recto 2		Verso 2	
Black		Black					
PMS 2355		PMS 2355					

A print out of this artwork should not be used for exact colour matching but to check if the layout, spelling, text and colour references are correct. Please check thoroughly.