

December 2023

Please note that there are currently 2 leaflets available for the CALPOL SIX PLUS SUSPENSION SUGAR FREE licence (PL 15513/0164).

It is the same product licence number for both leaflets i.e PL 15513/0164.

The information contained within each leaflet is identical apart from the manufacturer details.

1. PIL 1 (pages 2-3) – Manufacturer: Delpharm Orléans, 5 avenue de Concyr, 45071 Orléans, Cedex 2, France.

or

2. PIL 2 (pages 4-5) - Manufacturer: McNeil Iberica S.L.U., 28805 Madrid, Spain. This is a combined pdf of both leaflets.

Both these PILs are from different manufacturers as mentioned above and it will be inserted in carton as per its manufactured site.



SixPlus
Suspension
Sugar Free
Paracetamol
250 mg per 5 ml

- This medicine brings down high temperatures (also called fever) and relieves pain.
- The medicine is OK for most children over 6 years.
- **Do not give it to children on this list:**
 - Not to 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 SIXPLUS® Suspension Sugar Free is used to relieve pain and / or bring down fever (high temperature) in many conditions including cold and flu, headache, toothache, earache, post immunisation fever, 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.

X 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 any of these applies, **get advice from a doctor or**

pharmacist without using CALPOL®.

A 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)
 - cholestyramine (used to treat high cholesterol)
 - anticoagulants (drugs that thin the blood, such as warfarin)
 - anticonvulsants (drugs to treat epilepsy)
 - flucloxacilin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

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, talk to your doctor before you take this medicine. You may be more open to the side-effects of paracetamol. If this applies to you, talk to a doctor before use.
- 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.
- Ask your doctor or pharmacist for advice before taking this medicine if you are breastfeeding.

A Some of the ingredients can cause problems

- Methyl (E218) and propyl (E216)

parahydroxybenzoate may cause allergic reactions which could possibly be delayed.

- The sorbitol (E420) and maltitol content of this product means that this product is unsuitable for people with inherited intolerance to fructose.
- This medicine contains 1935 mg of sorbitol liquid (E420) per 5 ml dose which is equivalent to 390.6 mg/ml and 2.04 g maltitol liquid. Sorbitol is a source of fructose. If your doctor has told you that your child has an intolerance to some sugars or if your child has been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before your child receives this medicine.
- Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- Maltitol may have a mild laxative effect.
- Calorific values: 2.6 kcal/g sorbitol and 2.3 kcal/g maltitol.
- This medicine contains less than 1 mmol sodium (23 mg) per 5ml, that is to say essentially 'sodium-free'.
- This medicine contains 20.92mg propylene glycol (E1520) in each 5ml dose, which is equivalent to 4.18mg/ml.
- This medicine contains 0.05mg benzyl alcohol in each 5ml which is equivalent to 0.01mg/ml. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant or breastfeeding, or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

3 How to use this medicine

Check the table to see how much medicine to use.

- For oral use only.
- Always use the syringe supplied with the pack.
- It is important to **shake the bottle for at least 10 seconds before use.**
- Do not give anything else containing paracetamol while giving this medicine.
- Do not give more medicine than the label tells you to. If your child does not get better, talk to your doctor.

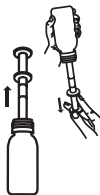
i How to use the syringe



- 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.

turn over ▶

(continued)



- 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 should be cleaned by hand without removing the plunger.

i Children under 6 years

Not recommended for children under 6 years old.
Ask your pharmacist to recommend a suitable product.

i Children from 6 years

| Child's Age | How much - up to 4 times a day |
|-----------------------------------|--------------------------------------|
| 6-8 years | 5 ml |
| 8-10 years | 7.5 ml (5 ml + 2.5 ml) |
| 10-12 years | 10 ml (5 ml + 5 ml) |
| 12-16 years | 10 - 15 ml (Two to three 5 ml doses) |
| Adults and children over 16 years | 10 - 20 ml (Two to four 5 ml doses) |

- 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.

! Speak to your doctor:

- If your child 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 SIXPLUS® Suspension Sugar Free 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, 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: CALPOL® is NOT intended for 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:

<http://www.mhra.gov.uk/yellowcard> or search for MHRA

Yellow Card in the Google Play or Apple App Store.

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.

Store in the original packaging.

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 250 mg per 5 ml.

Other ingredients are: Maltitol, sorbitol liquid (E420), glycerol, microcrystalline cellulose and carmellose sodium, xanthan gum, polysorbate 80, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), acesulfame potassium, saccharin sodium and purified water. The flavouring is imitation strawberry (containing propylene glycol (E1520) and benzyl alcohol).

What the medicine looks like

CALPOL SIXPLUS® Suspension Sugar Free is a white liquid, available in 80 ml. It contains 250 mg of the active ingredient Paracetamol in every 5 ml of medicine.

The Marketing Authorisation holder is McNeil Products Limited, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.

The manufacturer is Delpharm Orléans, 5 avenue de Concorcy, 45071 Orléans, Cedex 2, France.

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XXXXXX



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 - If s/he is taking anything else with paracetamol in it.
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pharmacist 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:
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 - *cholestyramine* (used to treat **high cholesterol**)
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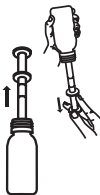


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turn over ▶



(continued)



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