

Please note that there are currently 2 leaflets available for the **Calpol Sugar Free Infant Suspension (100ml GSL bottle) [PL 15513/0123]**. Following SNAS BV 4110, this is a bulk type IB variation to update sections 4.4, 4.5 and 4.8 of the SmPC to bring in line with the PRAC recommendation dated 25 November 2024 (EMA/PRAC/499604/2024). Consequently, the PIL and label have been updated.

Both leaflets are applicable to the same product licence number namely, **PL 15513/0123**.

The information contained within each leaflet is identical apart from the manufacturer information, which is stated under “*What the medicine looks like*” of Section 6 (Contents of the pack and other information).

1. In PIL 1 (page 2):

Manufacturer: “**Delpharm Orleans, 5 avenue de Concyr, 45071 Orléans, Cedex 2, France.**”

2. In PIL 2 (page 4):

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.



**Sugar Free
Infant
Suspension**
Paracetamol
120 mg per 5 ml

- 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® Sugar Free Infant 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.

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 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 apply, **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.

During treatment with this medicine, tell your doctor straight away if:

- you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Other medicines and paracetamol

Please inform your doctor or pharmacist if you are taking:

- *metoclopramide* or *domeperidone* (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)
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

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. 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.

⚠ Some of the ingredients can cause problems

- Methyl (E218), propyl (E216) and ethyl (E214) parahydroxybenzoate may cause allergic reactions which could possibly be delayed.

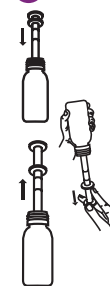
- The sorbitol (E420) and maltitol content of this product means that this product is unsuitable for people with inherited intolerance to fructose.
- This medicine contains 967 mg of sorbitol liquid (E420) per 5 ml dose which is equivalent to 193 mg/ml and 2.72 g maltitol liquid. Sorbitol is a source 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.
- Carmoisine (E122) may cause allergic reactions.
- This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially 'sodium-free'.
- This medicine contains 14.32 mg propylene glycol (E1520) in each 5 ml dose, which is equivalent to 2.86 mg/ml.
- This medicine contains 0.16 mg benzyl alcohol in each 5 ml which is equivalent to 0.03 mg/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 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. 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.

turn over ▶

- 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 Babies under 2 months

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

i 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.

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.

i 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.**

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

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[®] Sugar Free Infant 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, 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.
- a serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2). This side effect has a frequency

of "not known" which means it cannot be estimated from the available data.

If your child shows any of these signs, **stop giving paracetamol and talk to your 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: <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.

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, glycerol, polysorbate 80, sorbitol solution (E420), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), ethyl parahydroxybenzoate (E214), microcrystalline cellulose and carmellose sodium, xanthan gum and purified water. The flavouring is strawberry (containing propylene glycol (E1520) and benzyl alcohol) and colouring is carmoisine (E122).

What the medicine looks like

CALPOL[®] Sugar Free Infant Suspension is a pink liquid, available in 60 ml and 100 ml bottles. It contains 120 mg of the active ingredient paracetamol in every 5 ml of medicine.

MA holder: McNeil Products Limited, 50 – 100 Holmers

Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.

Manufacturer: Delpharm Orleans, 5 avenue de Concorc, 45071 Orléans, Cedex 2, France.

This leaflet was revised January 2025.

CALPOL[®] is a registered trade mark.

LN527004



**Sugar Free
Infant
Suspension**
Paracetamol
120 mg per 5 ml

- 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® Sugar Free Infant 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.

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 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 apply, **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.

During treatment with this medicine, tell your doctor straight away if:

- you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

⚠ Other medicines and paracetamol

Please inform your doctor or pharmacist if you are taking:

- **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**)
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

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. 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.

⚠ 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 (E420) and maltitol content of this product means that this product is unsuitable for people with inherited intolerance to fructose.
- This medicine contains 967 mg of sorbitol liquid (E420) per 5 ml dose which is equivalent to 193 mg/ml and 2.72 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.
- Carmoisine (E122) may cause allergic reactions.
- This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially 'sodium-free'.
- This medicine contains 14.32 mg propylene glycol (E1520) in each 5 ml dose, which is equivalent to 2.86 mg/ml.
- This medicine contains 0.16 mg benzyl alcohol in each 5 ml which is equivalent to 0.03 mg/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 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.

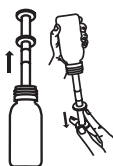
① How to use the syringe



- 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 ▶





- 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 Babies under 2 months

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

i 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.

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.

i 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.**

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

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® Sugar Free Infant 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, 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.
- a serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2). This side effect has a frequency of "not known" which means it cannot be estimated from the available data).

If your child shows any of these signs, **stop giving paracetamol and talk to your 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: <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.

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, glycerol, polysorbate 80, sorbitol solution (E420), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), ethyl parahydroxybenzoate (E214), microcrystalline cellulose and carmellose sodium, xanthan gum and purified water. The flavouring is strawberry (containing propylene glycol (E1520) and benzyl alcohol) and colouring is carmoisine (E122).

What the medicine looks like

CALPOL® Sugar Free Infant Suspension is a pink liquid, available in 60 ml and 100 ml bottles. It contains 120 mg of the active ingredient paracetamol in every 5 ml of medicine.

MA holder: McNeil Products Limited, 50 - 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.

Manufacturer: McNeil Iberica S.L.U., 28805 Madrid, Spain.

This leaflet was revised January 2025.