



**SixPlus  
FASTMELTS**

**Paracetamol**

250 mg tablets

- This medicine brings down high temperatures (also called fever) and relieves pain.
- This medicine is OK for most children over 6 years and adults.
- **Do not give it to anyone on this list:**
  - Not to anyone with phenylketonuria (a hereditary disease discovered at birth). *See section 2* ►
  - Not to anyone who is allergic to the ingredients. *See section 6* ►
  - Not to children or adults taking some other medicines. *See section 2* ►
- **Follow the dosage instructions carefully.** Children of different ages need different amounts. These are shown in the table. *See section 3* ►
- **Speak to your doctor** if anything in this list applies:
  - If your child needs more than the doses shown in the table, speak to your doctor as soon as possible. *See section 3* ►
  - If your child's pain or fever is not getting better after a few days talk to your doctor. *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 FASTMELTS® 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.

### ❌ 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 has phenylketonuria (a hereditary disease discovered at birth.)**

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

### ⚠️ Talk to your doctor or pharmacist...

- **If your child has serious kidney or liver problems.**

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.**

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## 2 Before giving the medicine to your child *(continued)*

### 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.

### ⚠ Some of the ingredients can cause problems

- This medicine contains 8 mg aspartame (E951) in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.
- This medicine contains mannitol (E421), which may have a mild laxative effect.

- This medicine contains 0.00064 mg benzyl alcohol in each tablet. 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").
- This medicine contains 0.0011 g glucose in each tablet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## 3 How to use this medicine

### Check the table to see how much medicine to use.

- For oral use only.
- To remove tablet use a fingernail to break the foil along the dotted line before pressing the tablet out.
- Tablets can be sucked gently until they melt on the tongue. There is no need to take water as they melt into a pleasant tasting paste which is easily swallowed.
- Alternatively, the tablets can be dissolved in a teaspoon of water or milk if preferred.
- 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.

### ⓘ Children under 6 years

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

### ⓘ Children from 6 years to adults

Child's Age	How much - up to 4 times a day
6-9 years	1 tablet
9-12 years	2 tablets
12-16 years	2-3 tablets

Adults and children over 16 years	2-4 tablets
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- 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, speak to your doctor as soon as possible.
- If your child's pain or fever is not getting better after a few days talk to your doctor.

### ⚠ 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 FASTMELTS® 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 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

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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. This medicinal product does not require any special storage conditions.

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 tablet.

**Other ingredients are:** Mannitol (E421), crospovidone, aspartame (E951), magnesium stearate, basic butylated methacrylate copolymer, polyacrylate dispersion 30% and colloidal anhydrous silica. The flavouring is strawberry (containing benzyl alcohol and glucose).

### **What the medicine looks like**

CALPOL SIXPLUS FASTMELTS® are white strawberry flavoured tablets which melt in your mouth, available in packs of 12 and 24 tablets. Each tablet contains 250 mg of the active ingredient paracetamol.

**The Marketing Authorisation holder** is McNeil Products Limited, High Wycombe, Buckinghamshire, HP12 4EG, UK.

**Manufacturer:** JNTL Consumer Health (France) SAS, Domaine de Maigremont, 27100 Val de Reuil, France.

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