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 apply, 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.
- 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)
- flucloxacillin (antibiotic), due to a serious risk of blood clots

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.

Now read this whole leaflet carefully before you use this medicine. Keep the leaflet: you might need it again.
2 Before giving the medicine to your child (continued)
■ 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 0.00064mg 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 0.0011g 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

<table>
<thead>
<tr>
<th>Child’s Age</th>
<th>How much - up to 4 times a day</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-9 years</td>
<td>1 tablet</td>
</tr>
<tr>
<td>9-12 years</td>
<td>2 tablets</td>
</tr>
<tr>
<td>12-16 years</td>
<td>2-3 tablets</td>
</tr>
</tbody>
</table>

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.

This section is continued on the next page.
4 Possible side-effects (continued)

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: 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.

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: Janssen-Cilag, Domaine de Maigremont, 27100 Val de Reuil, France.

This leaflet was revised May 2022

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