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Package leaflet: Information for the user



Read all of this leaflet carefully before you start using this medicine because it contains important information for you. Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If your child gets any side-effects, talk to your doctor or pharmacist. This includes any possible side-effects not listed in this leaflet. See section 4
- You must talk to a doctor if your child does not feel better or feels worse after 3 days.

What is in this leaflet

1. What Calpol is and what it is used for
2. What you need to know before you use Calpol
3. How to take Calpol
4. Possible side-effects
5. How to store Calpol
6. Contents of the pack and other information

## 1 What Calpol is and what it is used for

The paracetamol in Calpol Six Plus Fastmelts is used to relieve pain such as tooth pain, headache, sore throat and aches and pains that come with colds and flu. It also brings down fever (high temperature).

## 2 What you need to know before you use Calpol

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

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

**Warnings and precautions**

Talk to your doctor or pharmacist...

- If your child has serious kidney or liver problems.

**Other medicines and Calpol**

**Tell your doctor or pharmacist 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.

**Calpol Fastmelts contains aspartame**

- Aspartame (E951) contains a source of phenylalanine which may be harmful for people with phenylketonuria.

## 3 How to use Calpol Fastmelts

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Check the tables below to see how much medicine to use.**

- 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 use more medicine than shown in the table.

**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

- 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.

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6 mm

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Barcodes placed at 14 mm  
Height for bars : 10 mm

spot = 12 x 2 centered in  
the margin of 14 mm

Distance between cutted line/middle of the spot = 83.6 mm

14 reading way

left margin 12 mm

right margin 14 mm

6 mm

## 3 How to use Calpol Fastmelts (continued)

**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**

Immediate medical advice should be sought in the event of an overdose, even if the child seems well, because of the risk of delayed, serious liver damage.

**If you forget to give Calpol**

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

Like all medicines, this medicine can cause side-effects although not everybody gets them.

**Stop using this medicine and contact your doctor immediately if you experience:**

- Severe skin reactions. Symptoms may include, skin reddening, blisters, rash.

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

- skin rashes or other signs of allergy.
- 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.

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

**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.

**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 HPPA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side-effects you can help provide more information on the safety of this medicine.

## 5 How to store Calpol

Store in the original package.

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

This medicinal product does not require any special temperature 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 any medicines you no longer use. These measures will help protect the environment.

## 6 Contents of the pack and other information

**What Calpol contains**

**The active substance is:** paracetamol 250 mg per tablet

**Other ingredients are:** Mannitol (E421), crospovidone, aspartame (E951), magnesium stearate, polymethacrylates and colloidal anhydrous silica. The flavouring is strawberry.

**What Calpol looks like and contents of the pack**

Calpol Six Plus Fastmelts are white strawberry flavoured tablets which melt in your mouth, available in packs of 12 tablets.

Each tablet contains 250 mg of the active ingredient Paracetamol.


**Marketing Authorisation Holder and Manufacturer**

**The Product Authorisation holder** is McNeil Healthcare (Ireland) Ltd, Airton Road, Tallaght, Dublin 24, Ireland.

**The manufacturer** is Janssen Cilag, Domaine de Maignemont, 27100 Val de Reuil, France.

**This leaflet was last revised in October 2014.**

Calpol is a registered trade mark.



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Johnson & Johnson		COLOURS:			
Job Bag No.	14-0206	PMS 485	PMS 2612	PMS Black	Profile
Version	3				
Product	Calpol 6+				
Description	6+ Fastmelts PIL				
Country	IRE				
Date	15/10/2014				
Manufacturer	Val De Reuil				
Software	Illustrator CS6				
		SIZE:		Main body text (PIL's only)	
		210 x 145 mm		7.5 pts	
A print out of this image should not be used for exact colour matching but to check if the layout, spelling, text and colour references are correct. Please check thoroughly.					