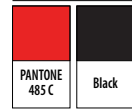


Project Name / Design	IE_Calpol Six Plus Fastmelts_12's Leaflet (SNAS BV 3744) (CRD 11699)		
New Component / Item Code	360135J	ArtWorks ID	EMEA_2023_00093808_000
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		Date	15-05-2023



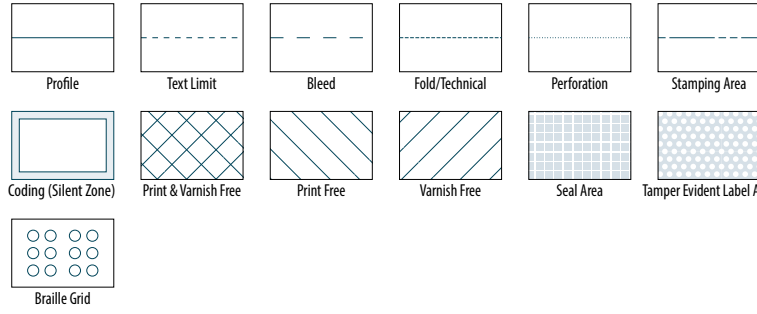
REPRESENTATION: Colours represented with a diagonal line have been modified to aid PDF approval.

MANUFACTURING SITE

Reference	F_I_006	Technical Code	962
Substrate	WHITE	PC-Spec	PC-0002781

TECHNICAL DETAILS

Component	Simple Leaflet	Plant	Val De Reuil
Dimensions	145 x 250 mm	Master Dieline	JJSC_00023_V3_P
		Date	28-10-2022



FONTS USED

Gotham-Bold
Gotham-Medium
HelveticaNeueLTStd-BdCn
HelveticaNeueLTStd-Cn
HelveticaNeueLTStd-CrO
ZapfDingbatsITC

SMALLEST TEXT SIZE

4.66 pt

AVE. TEXT SIZE

8 pt

LARGEST TEXT SIZE

22.90 pt

Package leaflet: information for the user

Calpol® SixPlus FASTMELTS 250 mg Paracetamol Orodispersible Tablets

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 use 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 SIXPLUS 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®

⚠ Do not give your child this medicine...

- if s/he has ever had a bad reaction to paracetamol or any of the other ingredients in this medicine (see section 6).
- 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®.

⚠ Warnings and precautions

- Talk to your doctor or pharmacist...
- if your child has serious kidney or liver problems.
- if your child has Gilbert's syndrome (familial non-haemolytic jaundice).
- if your child has a condition called Glucose-6-phosphate dehydrogenase deficiency.
- if your child has haemolytic anaemia.
- if your child has glutathione deficiency.
- if your child is dehydrated or chronically malnourished.

⚠ Other medicines and Calpol®

- Tell your doctor or pharmacist if you or 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)
 - flucloxacillin (an 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 kidney 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.

- medicines that can affect liver function. 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 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.
- If you are breastfeeding, ask your doctor or pharmacist for advice before taking this medicine.
- If you weigh less than 50 kg, ask your doctor or pharmacist for advice before taking this medicine.
- If you are elderly and are frail or immobile or you have kidney or liver problems, you should ask your doctor or pharmacist for advice before taking this product, as you may need to take a reduced dose.

⚠ Calpol® Fastmelts contains aspartame, benzy alcohol and glucose

- 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 0.00064mg benzy alcohol per tablet. Benzy 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 benzy alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").
- This medicine contains glucose, if you have been told by your doctor to turn over



doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3 How to use Calpol®

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 overleaf to see how much medicine to use.

- To remove a 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.

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.

By reporting side-effects you can help provide more information on the safety of this medicine.

5 How to store Calpol®

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

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

Store in the original package.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

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. Each orodispersible tablet contains 250 mg paracetamol.

The other ingredients are: Mannitol (E421), crospovidone (type A), aspartame (E951), magnesium stearate, polymethacrylates and silica hydrophobic colloidal anhydrous. The flavouring is strawberry (containing benzy alcohol and glucose).

What Calpol® looks like and contents of the pack

CALPOL SIXPLUS FASTMELTS™ are white, round, strawberry flavoured tablets which melt in your mouth, available in packs of 12 or 24 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation holder is Johnson & Johnson (Ireland) Ltd, Airton Road, Tallaght, Dublin 24, Ireland.

The manufacturer is JNLT Consumer Health (France) SAS, Domaine de Maigremont, 27100 Val de Reuil, France.

This leaflet was last revised in May 2023

CALPOL® is a registered trade mark. 360135J

⚠ 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:

- Allergic reactions including unexplained wheezing, shortness of breath, passing out or swelling of face and throat.
- 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 and are due to changes in blood cells.

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, Website: www.hpra.ie