SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Calpol Infant Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Paracetamol Ph. Eur 120mg in 5 ml.

Excipients with known effect:
Sorbitol 70% solution
Propylene glycol
Carmoisine
Methyl parahydroxybenzoate

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

For the treatment of mild to moderate pain (including teething pain), and as an antipyretic.

4.2. Posology and Method of Administration

The lowest dose necessary to achieve efficacy should be used.
Do not exceed the stated dose.

<table>
<tr><th>Age : 2 – 3 months</th><th>Dose</th></tr>
<tr><td>1. Post-vaccination fever</td><td rowspan="2">2.5 ml
If necessary, after 4-6 hours, give a second 2.5 ml dose</td></tr>
<tr><td>2. Other causes of Pain and Fever - if your baby weighs over 4 kg and was born after 37 weeks</td></tr>
<tr><td colspan="2">• Do not give to babies less than 2 months of age.
• Do not give more than 2 doses.
• Leave at least 4 hours between doses.
• If further doses are needed, talk to your doctor or pharmacist.</td></tr>
</table>

Children aged 3 months – 6 years:

Child's Age	How Much	How often (in 24 hours)
3 – 6 months	2.5 ml	4 times
6 – 24 months	5 ml	4 times
2 – 4 years	7.5 ml (5 ml + 2.5 ml)	4 times
4 – 6 years	10 ml (5 ml + 5 ml)	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.

Use in the Elderly

In the elderly the dosage of paracetamol is 500 mg to 1 g every 4 to 6 hours up to a maximum of 4 g daily as the rate and extent of paracetamol absorption is normal. The dosage may need to be adjusted as the plasma half-life is longer and paracetamol clearance is lower than in young adults.

4.3. Contra-indications

This product is contra-indicated in patients with known hypersensitivity to paracetamol.

4.4. Special Warnings and Precautions for Use

Contains paracetamol. Do not use with any other paracetamol- containing products. The concomitant use with other products containing paracetamol may lead to an overdose.

Paracetamol overdose may cause liver failure which can lead to liver transplant or death.

Calpol Infant Suspension should be used with caution in severe hepatic or renal dysfunction.

Cases of hepatic dysfunction/failure have been reported in patients with depleted glutathione levels, such as those who are severely malnourished, anorexic, have a low body mass index or are chronic heavy users of alcohol.

In patients with glutathione depleted states such as sepsis, the use of paracetamol may increase the risk of metabolic acidosis.

Sorbitol: This medicine contains 1.2215 mg sorbitol in each 5 mL oral suspension which is equivalent to 0.244 mg/mL. Patients with hereditary fructose intolerance (HFI) should not take/be given this medicine.

Sodium: This medicine contains less than 1 mmol sodium (23 mg) per 5 mL, that is to say essentially ‘sodium-free’.

Propylene glycol: This medicine contains less than 1 mg propylene glycol per 5 mL of oral solution which is equivalent to less than 1 mg/kg/day. Co-administration with any substrate for alcohol dehydrogenase such as ethanol may induce serious adverse effects in neonates.

This medicine contains carmoisine which may cause allergic reactions.

This medicine contains methyl parahydroxybenzoate which may cause allergic reactions (possibly be delayed).

Calpol Infant Suspension should not be diluted.

The label contains the following statements:
Do not exceed the recommended dose.
If symptoms persist consult your doctor.
Keep out of the reach and sight of children.
Leave at least 4 hours between doses.
Immediate advice should be sought in the event of an overdose, even if the child seems well. (label)
Immediate 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. (leaflet)

Do not give with any other paracetamol containing products.

4.5. Interactions with other Medicaments and other forms of Interaction

Patients who have taken barbiturates, tricyclic antidepressants, and alcohol may show diminished ability to metabolise large doses of paracetamol, the plasma half-life of which can be prolonged. Alcohol can increase the hepatotoxicity of paracetamol overdosage and may have contributed to the acute pancreatitis reported in one patient who had taken an overdose of paracetamol.

Chronic ingestion of anticonvulsants or oral steroid contraceptives induce liver enzymes and may prevent attainment of therapeutic paracetamol levels by increasing first pass metabolism or clearance.

4.6. Pregnancy and Lactation

Data are not available on the use of Calpol Infant Suspension during pregnancy. There is epidemiological evidence of safety of paracetamol in human pregnancy.

A pharmacokinetic study in 12 nursing mothers revealed that less than 1% of the dose ingested by a nursing mother appears in human milk. Therefore maternal ingestion of the therapeutic doses does not present a risk to the infant.

4.7. Effects on Ability to Drive and Use Machines

None known.

4.8. Undesirable Effects

Paracetamol has been widely used and when taken at the usual recommended dosage side effects are mild and infrequent and reports of adverse reactions are rare.

Skin rashes and other allergic reactions occur rarely.

Most reports of adverse reactions to paracetamol relate to overdosage with the drug.

Isolated cases of thrombocytopenic purpura, heamolytic anaemia and agranulocytosis have been reported.

Chronic hepatic necrosis has been reported in a patient who took daily therapeutic doses of paracetamol for about a year and liver damage has been reported after daily ingestion of excessive amounts for shorter periods. A review of a group of patients with chronic active hepatitis failed to reveal differences in the abnormalities of liver function in those who were long-term users of paracetamol nor was the control of their disease improved after paracetamol withdrawal.

Nephrotoxicity following therapeutic doses of paracetamol is uncommon, but papillary necrosis has been reported after prolonged administration.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system. ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

4.9. Overdose

Paracetamol overdose may cause liver failure which can lead to liver transplant or death.

Pallor, anorexia, nausea and vomiting are frequent early symptoms of paracetamol overdosage. Hepatic necrosis is a dose-related complication of paracetamol overdosage. Hepatic enzymes may become elevated and prothrombin time prolonged within 12-18 hours but clinical symptoms may not be apparent until 1 to 6 days after ingestion. Toxicity is likely in adults who have taken more than 10g.

To protect the patient against delayed hepatotoxicity, paracetamol overdosage should be treated promptly by gastric lavage followed by intravenous N-acetylcysteine or oral methionine. Additional therapy (further methionine or intravenous N-acetylcysteine) is normally considered in the light of blood paracetamol content and time elapsed since ingestion. Fulminant hepatic failure which may follow paracetamol overdosage requires specialised management.

In paracetamol overdosage with liver cell damage paracetamol half-life is often prolonged from around 2 hours in normal adults to 4 hours or longer, However, liver cell damage has been found in patients with a paracetamol half-life less than 4 hours. Diminution in $^{14}CO_2$ excretion after oral ^{14}C-aminopyrine has been reported to correlate better with liver cell damage in paracetamol overdosage than do either plasma paracetamol concentration or half-life or conventional liver function test measurements. Concomitant renal failure due to acute tubular necrosis may accompany paracetamol-induced fulminant hepatic failure. The incidence is, however, no more frequent in these patients than in other with fulminant hepatic failures from other causes.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Paracetamol has analgesic and antipyretic properties that do not differ significantly from those of aspirin. However it has only weak anti-inflammatory effects. It is only a weak inhibitor of prostaglandin biosynthesis although there is some evidence to suggest it may be more effective against enzymes in the central nervous system than in the periphery. This may in part account for its activity profile.

5.2. Pharmacokinetic Properties

Paracetamol is rapidly and almost completely absorbed from the gastro-intestinal tract with peak plasma concentrations occurring 0.5-2 hours after dosing. The plasma half-life is approximately 2 hours after therapeutic doses in adults but is increased in neonates to about 5 hours. It is widely distributed through the body. Metabolism is principally by the hepatic microsomal enzymes and urinary excretion accounts for over 90% of the dose within 1 day. Virtually no paracetamol is excreted unchanged, the bulk being conjugated with glucuronic acid (60%), sulphuric acid (35%) or cysteine (3%). Children have less capacity for glucuronidation of the drug than adults.

5.3. Preclinical Safety Data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. Pharmaceutical Particulars

6.1. List of Excipients

Syrup	BP	
Sorbitol Solution	PH.EUR	
Glycerol	PH.EUR	
Xanthan Gum	USNF	
Strawberry Flavour (contains propylene glycol)		HSE
Methyl parahydroxybenzoate	PH.EUR	
Carmoisine (El22) (contains sodium)	HSE	
Purified Water	PH. EUR	

6.2. Incompatibilities

None known.

6.3. Shelf Life

36 months

6.4. Special Precautions for Storage

Store below 25°C, protect from light.

6.5. Nature and Contents of Container

Amber glass bottles closed with a two-piece or three-piece child resistant, tamper evident closure fitted with a polyethylene/polyvinylidene chloride (PVDC)/polyethylene laminate faced wad.

Pack size: 70ml, 100ml, 140ml, 200ml.

6.6. Instruction for Use/Handling

None applicable.

7. MARKETING AUTHORISATION HOLDER

GlaxoSmithKline (Ireland) Limited
12 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8. MARKETING AUTHORISATION NUMBER

MA192/03701

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

30th October 2006/22nd October 2014

10. DATE OF REVISION OF THE TEXT

12th April 2024