# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT

Calpol Sugar-Free Infant Suspension.

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Paracetamol Ph. Eur 120mg in each 5ml.

Excipients with known effect:
Maltitol solution
Sorbitol 70% solution
Propylene glycol
Carmoisine
Methyl parahydroxybenzoate
Propyl 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<br>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.<br>• Do not give more than 2 doses.<br>• Leave at least 4 hours between doses.<br>• 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<br>• Leave at least 4 hours between doses<br>• 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.

For oral administration.

## 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 Sugar-Free 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 0.525 mg sorbitol in each 5 mL which is equivalent to 0.105 mg/mL. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly.

Maltitol solution: This medicine contains 2 mL maltitol solution in each 5 mL. Patients with rare hereditary problems of fructose intolerance should not take 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. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

This medicine contains carmoisine which may cause allergic reactions.

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

Store below 25ºC
Protect from light
Contains paracetamol
Keep out of reach of children
Do not exceed the stated dose
Do not take more than 4 doses in 24 hours
Do not repeat doses more frequently than 4 hourly
Do not give for more than 3 days without consulting a doctor
In case of accidental overdose seek medical attention immediately
If you are currently taking any other medicine consult your doctor or pharmacist before taking this product
If symptoms persist consult your doctor

## 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 Sugar-Free 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, haemolytic anaemia and agranulocytosis have been recorded.

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. 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 ReportingWebsite: www.medicinesauthority.gov.mt

## 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 12-48 hours but clinical symptoms may not be apparent for 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 cysteamine 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 $^{14}CO_2$ 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 others with fulminant hepatic failure from other causes.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1. Pharmacodynamic Properties

Paracetamol has analgesic and antipyretic properties similar to those of aspirin and is useful in the treatment of mild to moderate pain. It has only weak anti-inflammatory effects.

### 5.2. Pharmacokinetic Properties

Paracetamol is rapidly and almost completely absorbed from the gastro-intestinal tract. Peak plasma concentrations are reached 30-90 minutes post dose and the plasma half-life is in the range of 1 to 3 hours after therapeutic doses. Drug is widely distributed throughout most body fluids. Following therapeutic doses 90-100% of the drug is recovered in the uringe within 24 hours almost entirely following hepatic conjugation with glucuronic acid (about 60%), sulphuric acid (about 35%) or cysteine (about 3%). Small

amounts of hydroxylated and deacetylated metabolites have also been detected. Children have less capacity for glucuronidation of the drug than do adults. In overdosage there is increased N-hydroxylation followed by glutathione conjugation. When the latter is exhausted reaction with hepatic proteins is increased leading to necrosis.

### 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

| | |
|---|---|
| Maltitol Solution | USNF |
| Sorbitol Solution (70% non-crystallising) | PH.EUR |
| Glycerol | PH.EUR |
| Dispersible Cellulose | BP |
| Xanthan Gum | USF |
| Methyl parahydroxybenzoate | PH. EUR |
| Propyl parahydroxybenzoate | PH.EUR |
| Strawberry Flavour 500286E (contains propylene glycol) | HSE |
| Carmoisine E122 (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 bottle 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: 30ml, 70ml, 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

MA192/03703

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

30th October 2006/22nd October 2014

## 10. DATE OF REVISION OF THE TEXT

12th April 2024