SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Junior Paracetamol Suspension

Boots Pain Relief Paracetamol Suspension 3 Months Plus

Galpamol for Children Paracetamol 120mg/5ml Oral Suspension

Infant's & Children's Paracetamol Suspension

Boots Paracetamol Sachets 3 Months Plus 120 mg/5 ml Oral Suspension

Galpharm Childrens Paracetamol 120mg/5ml Oral Suspension

Paracetamol 120mg/5ml Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Paracetamol 120 mg / 5 ml

Excipients with known effect:

Each 120mg/5ml dosage contains:

Sodium Methylparaben (E219) 8.750 mg
Sodium Propylparaben (E217) 1.000 mg
Strawberry Flavour D3694 8mg (containing 7mg Propylene Glycol)
Hydrogenated Glucose Syrup-consists of 260mg Sorbitol (E420) and 1,787.50mg Maltitol (E965)

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Oral Suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For relief of mild to moderate pain including teething pain, and for pyrexia.

4.2. Posology and Method of Administration

For oral administration. It is important to **shake the bottle** for at least 10 seconds before use.

For children aged 3 months to 12 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 – 8 years	10 ml (5 ml + 5 ml)	4 times
8 – 10 years	15 ml (5 ml + 5 ml + 5ml)	4 times
10 - 12 years	20 ml (5 ml + 5 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

Babies over 2 months in age
For the relief of fever after vaccination at 2, 3 and 4 months
2.5ml. This dose may be given up to 4 times a day at the time of vaccination. Do not give more than 4 doses in any 24 hour period. Leave at least 4 hours between doses. If your baby still needs this medicine two days after receiving the vaccine talk to your doctor or pharmacist.

4.3 Contraindications

Contra-indicated in patients with a known hypersensitivity to paracetamol or any of the other constituents.

4.4 Special warnings and precautions for use

Care is advised in the administration of paracetamol to patients with renal or hepatic impairment. The hazard of overdose is greater in those with non- cirrhotic alcoholic liver disease.

Excessive intake of caffeine (e.g. coffee, tea and some canned drinks) should be avoided while taking this product.

Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition or other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring, is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients with multiple risk factors.

Do not exceed the stated dose.

Patients should be advised to consult their doctor if their headaches become persistent.

Patients should be advised not to take other paracetamol-containing products concurrently.

Each 2 tablet dose contains 854 mg of sodium and should not be taken by patients on a low sodium diet. This medicinal product contains 427 mg sodium per effervescent tablet, equivalent to 21% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

If symptoms persist consult your doctor. Keep out of the reach and sight of children.

<u>Pack label</u>

Immediate medical advice should be sought in the event of an overdose, even if you feel well.

Do not take with any other paracetamol-containing products.

Patient Information Leaflet

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

4.5 Interaction with other medicinal products and other forms of interaction

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine. The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis due to pyroglutamic acidosis, especially in patients with risks factors (see section 4.4)

4.6 Fertility, pregnancy and lactation

A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contra-indicate breast feeding.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Adverse events from historical clinical trial data are both infrequent and from small patient exposure. Accordingly, events reported from extensive post- marketing experience at therapeutic/labelled dose and considered attributable are tabulated below by system class. Due to limited clinical trial data, the frequency of these adverse events is not known (cannot be estimated from available data), but post-marketing experience indicates that adverse reactions to paracetamol are rare and serious reactions are very rare.

Post marketing data

Body System	**Undesirable effect**
Blood and lymphatic system disorders	Thrombocytopenia Agranulocytosis
Immune system disorders	Anaphylaxis Cutaneous hypersensitivity reactions including skin rashes, angioedema and Stevens Johnson syndrome/toxic epidermal necrolysis
Respiratory, thoracic and mediastinal disorders	Bronchospasm*
Hepatobiliary disorders	Hepatic dysfunction

Metabolism and nutrition disorders	High anion gap metabolic acidosis* have been reported frequency is Not known

* There have been cases of bronchospasm with paracetamol, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs.

*Cases of high anion gap metabolic acidosis due to pyroglutamic acidosis have been observed in patients with risk factors using paracetamol (see section 4.4). Pyroglutamic acidosis may occur as a consequence of low glutathione levels in these patients.

Caffeine	
Central Nervous system	Nervousness Dizziness
When the recommended paracetamol-caffeine dosing regimen is combined with dietary caffeine intake, the resulting higher dose of caffeine may increase the potential for caffeine-related adverse effects such as insomnia, restlessness, anxiety, irritability, headaches, gastrointestinal disturbances and palpitations.	

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Early symptoms of paracetamol overdosage include pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning hepatic failure may progress to encephalopathy, coma and death. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported. Liver damage is possible in adults who have taken 10g of more of paracetamol. It is considered that excess quantities of a toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested), become irreversibly bound to liver tissue.

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Any patient who has ingested around 7.5g or more of paracetamol in the preceding 2 hours should undergo gastric lavage. Administration of oral methionine or intravenous n-acetylcysteine which may have a beneficial effect up to at least 48 hours after the overdose, may be required. General supportive measures must be available.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Paracetamol has analgesic and antipyretic actions probably due to the inhibition of prostaglandin biosynthesis.

5.2 Pharmacokinetic properties

Paracetamol is readily absorbed from the gastro-intestinal tract and peak plasma concentrations usually occur 30 minutes to 2 hours after ingestion. Paracetamol is metabolised in the liver and largely excreted in the urine as sulphate and glucuronide conjugates. Less than 5% is excreted unchanged. The elimination half-life varies from about 1 to 4 hours.

5.3 Preclinical safety data

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol; Dispersible Cellulose; Sodium Methylparaben; Sodium Propylparaben; Citric Acid Anhydrous; Saccharin Sodium; Strawberry Flavour D3694 (containing Propylene Glycol); Acesulphame K; Carmine Extract P4011 (containing Carmine, Glycerine, Potassium Hydroxide); Hydrogenated Glucose Syrup; Xanthan Gum; Purified Water.

6.2 Incompatibilities

None

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C. Do not refrigerate. Protect from light.

6.5 Nature and contents of container

Amber glass or PET bottles with polyethylene child resistant screw closures, containing 70, 100, 150 or 200 ml.

5ml unit dose foil laminate sachets sold individually or packed into cartons containing 4, 5, 8, 10, 12, 15, 16, 20, 24, 25, 48, 50, 70, 96 or 100.

6.6 Special precautions for disposal

Not applicable

7. MARKETING AUTHORISATION HOLDER

Galpharm Healthcare Limited
Wrafton
Braunton
Devon
EX33 2DL
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 16028/0118

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27/07/1995 / 23/02/2009

10 DATE OF REVISION OF THE TEXT

10/04/2025