

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Panadol Baby 120 mg/5 ml, Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml measure of suspension contains paracetamol 120mg.

Excipients: Each 5ml contains: Sorbitol 0.75g, Maltitol 2.7g, and Parahydroxybenzoates 12.2mg (E216, E218).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension

Opaque to translucent, white to slightly brownish suspension..

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Panadol Baby suspension is recommended for the relief of pains of teething, toothache and sore throats and for reducing the fever often associated with colds and 'flu' and childhood infections such as chicken pox, whooping cough, measles and mumps.

4.2 Posology and method of administration

This product is intended for oral use in children ages:

Age : 2 – 3 months	Dose
1. Post-vaccination fever	2.5 mL
	If necessary, after 4-6 hours, give a second 2.5 mL dose
1. Other causes of pain and fever <u>only</u>if <ul style="list-style-type: none"> ○ Weighs over 4 kg ○ Born after 37 weeks 	
<ul style="list-style-type: none"> • 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 	

Child's Age	How Much	How often (in 24 hours)
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3 – 6 months	2.5 mL	4 times
6 – 24 months	5 mL	4 times
2 – 4 years	7.5 mL	4 times
4 – 8 years	10 mL	4 times
8 – 10 years	10 mL + 5 mL	4 times
10 – 12 years	10 mL + 10 mL	4 times

- Do not give more than 4 doses in any 24 hour period
- Leave at least 4 hours between doses
- The lowest dose necessary to achieve efficacy should be used.
- 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

If your baby was born prematurely and is less than 3 months old consult your doctor prior to use.

Method of Administration

Panadol Baby suspension is for oral administration only.

Using the accurate dosing device



1 INSERT

Push the plunger fully in to close the dosing device; then insert it firmly in to the neck of the bottle.



2 SLIDE TO THE CORRECT DOSE

Turn the bottle upside down and gently pull the correct dose for your child. The correct dose is at the point where the widest sides of the plunger meets the correct mL mark on the barrel of the dosing device.



3 REMOVE

Turn the bottle upright and remove from the neck of the bottle by gently twisting it.

After using this medicine

- Push the cap down and turn it to close cap tightly, then turn backward until you hear clicking sounds.

After use you should clean the device with warm water and dry it, no need for sterilisation of the device.

4.3 Contraindications

Hypersensitivity to paracetamol or any of the other constituents.

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.

Underlying liver disease increases the risk of paracetamol related liver damage. Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication.

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.

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 and 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.

If symptoms persist, consult your doctor. Prolonged use except under medical supervision may be harmful. This product should only be used when clearly necessary. Keep out of the sight and reach of children.

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

This product is intended for use in children.

Pregnancy

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.

Lactation

Paracetamol is excreted in breast milk. However, the level of paracetamol present is not considered to be harmful. Available published data do not contraindicate breastfeeding.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Events reported from extensive post-marketing experience at therapeutic/labelled dose and considered attributable are tabulated below by System Organ Class and frequency.

Frequencies are defined as: very common ($\geq 1/10$), common ($\geq 1/100$, $< 1/10$), uncommon ($\geq 1/1,000$, $< 1/100$), rare ($\geq 1/10,000$, $< 1/1,000$), very rare ($< 1/10,000$), not known (cannot be estimated from available data).

Adverse event frequencies have been estimated from spontaneous reports received through post marketing data.

Body System	Undesirable Effect	Frequency
Paracetamol		
Blood and lymphatic system disorders	Thrombocytopaenia	Very rare
Metabolism and nutrition disorders	High anion gap metabolic acidosis*	Not known
Immune System disorders	Anaphylaxis, Cutaneous hypersensitivity reactions, including, among others, skin rashes, angiodema, Stevens Johnson syndrome and Toxic Epidermal Necrolysis. Very rare cases of serious skin reactions	Very rare
Respiratory, thoracic and mediastinal disorders	Bronchospasm in patients sensitive to aspirin and other NSAIDs	Very rare
Hepatobiliary disorders	Hepatic dysfunction	Very rare

* 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.

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 HPRA Pharmacovigilance, website: www.hpra.ie.

4.9 Overdose

Paracetamol overdose may cause liver failure which can lead to liver transplant or death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity

There is a risk of poisoning with paracetamol particularly in elderly subjects, young children, patients with liver disease, cases of chronic alcoholism and in patients with chronic malnutrition. Overdosing may be fatal in these cases.

Symptoms generally appear within the first 24 hours and may comprise: nausea, vomiting, anorexia, pallor, and abdominal pain, or patients may be asymptomatic.

Overdose of paracetamol in a single administration in adults or in children can cause liver cell necrosis likely to induce complete and irreversible necrosis, resulting in hepatocellular insufficiency, metabolic acidosis and encephalopathy which may lead to coma and death. Simultaneously, increased levels of hepatic transaminases (AST, ALT), lactate dehydrogenase and bilirubin are observed together with increased prothrombin levels that may appear 12 to 48 hours after administration.

Liver damage is likely in adults who have taken more than the recommended amounts of paracetamol. It is considered that excess quantities of toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested), become irreversibly bound to liver tissue.

Some patients may be at increased risk of liver damage from paracetamol toxicity.

Risk Factors include: If the patient;

- Is on long-term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.
- Regularly consumes ethanol in excess of recommended amounts
- Is likely to be glutathione depleted e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia

Emergency Procedure:

Immediate transfer to hospital.

Blood sampling to determine initial paracetamol plasma concentration. In the case of a single acute overdose, paracetamol plasma concentration should be measured 4 hours post ingestion.

Administration of activated charcoal should be considered if >150mg/kg paracetamol has been taken within 1 hour.

The antidote N-acetylcysteine, should be administered as soon as possible in accordance with National treatment guidelines.

Symptomatic treatment should be implemented.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code/pharmacotherapeutic group: N02BE01
Paracetamol has analgesic and antipyretic actions.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. Concentration in plasma generally reaches a peak in 30-60 minutes; plasma half-life is 1-4 hours. It is metabolised in the liver and excreted in the urine, mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unmodified paracetamol.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of this SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol (70%) Liquid, non-crystallising
Xanthan gum
Methyl parahydroxybenzoate
Propyl parahydroxybenzoate
Citric acid anhydrous
Tri-Sodium citrate dihydrate
Glycerin
Strawberry flavour
Disodium EDTA
Sucralose
Maltitol syrup
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Amber glass bottles fitted with Clic-loc closures with expanded polyethylene/polypropylene liners. Pack sizes: 60ml and 100ml.

10 mL plastic dosing syringe consists of a barrel (body) & plunger (slider) made from Polyethylene and Polypropylene plastic grades.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Haleon Ireland Limited,
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Co. Waterford, X35 Y983,
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8 MARKETING AUTHORISATION NUMBER

PA0678/039/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 December 1992

Date of last renewal: 22 December 2007

10 DATE OF REVISION OF THE TEXT

July 2025