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** o Weighs over 4 kg o Born after 37 weeks	
• **Do not give to babies less than 2 months ofage** • **Do not give more than 2 doses** • **Leave at least 4 hours betweendoses** • **If further doses are needed, talk to your doctor orpharmacist**	

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**	**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**

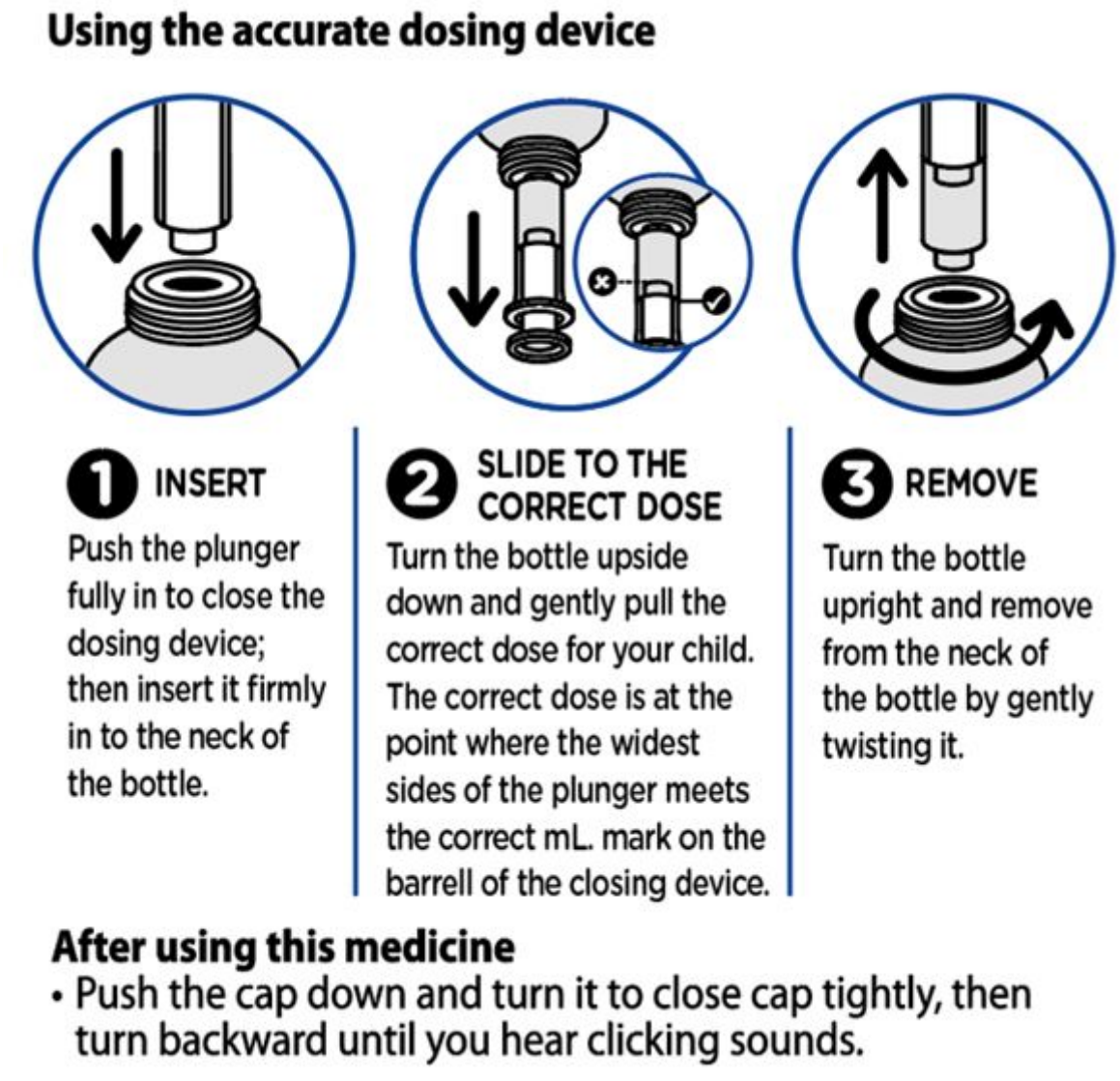
• **Do not give more than 4 doses in any 24 hourperiod** • **Leave at least 4 hours betweendoses** • **The lowest dose necessary to achieve efficacy should beused.** • **Do not give this medicine to your child for more than 3 days without speaking to your doctor orpharmacist**		

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.



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 give 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. 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.

Caution is advised if paracetamol is administered concomitantly with flucloxacillin due to increased risk of high anion gap metabolic acidosis (HAGMA), particularly in patients with severe renal impairment, sepsis, malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism), as well as those using maximum daily doses of paracetamol. Close monitoring, including measurement of urinary 5-oxoproline, is recommended.

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.
Caution in patients with glutathione depleted states such as sepsis; the use of paracetamol may increase the risk of metabolic acidosis.

Never give more medicine than shown in the table. Do not overfill the measuring device.
Always use the measuring device supplied with the pack. Do not give to babies less than 2 months of age.
For infants 2-3 months no more than 2 doses should be given. 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.
As with all medicines, if your child is currently taking any medicine consult your doctor or pharmacist before taking this product.

Keep out of the sight and reach of children. If symptoms persist, consult your doctor.
Prolonged use except under medical supervision may be harmful.

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

If your child has a known intolerance to some sugars, contact your doctor before use as this product contains maltitol syrup and sorbitol.

Immediate medical advice should be sought in the event of an overdose, even if the patient feels well because of the risk of irreversible liver damage.

Contains parahydroxybenzoates (E216 and E218) which may cause allergic reactions, possibly delayed.

Maltitol & Sorbitol liquid:

Patients with rare hereditary problems of fructose intolerance should not take this medicine. Each 120mg/5 ml suspension contains sorbitol (E 420) at 750 mg per 5 ml suspension. This medicine may have a mild laxative effect and cause gastrointestinal discomfort.

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, 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

There have been rare reports of blood dyscrasias including thrombocytopenia and agranulocytosis but these were not necessarily causally related to paracetamol.

The frequency of adverse events associated with paracetamol is tabulated below.

Body System	Undesirable Effect	Frequency
Paracetamol		
Blood and lymphatic system disorders	Thrombocytopaenia	Very rare
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 have been reported	Very rare
Respiratory, thoracic and mediastinal disorders	Bronchospasm in patients sensitive to aspirin and other NSAIDs	Very rare
Hepatobiliary disorders	Hepatic dysfunction	Very rare

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
Paracetamolhas 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
12 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

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 2024