SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Panadol Baby and Infant Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml spoonful of suspension contains Paracetamol Ph.Eur. 120mg

(Paracetamol Ph.Eur. 2.40% w/v)

3 PHARMACEUTICAL FORM

Aqueous suspension

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Panadol Baby and Infant Suspension is recommended for the relief of pains of teething, toothache and sore throats and for reducing the feverishness 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 use in children.

For oral administration only.

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

Children aged 3 months and above:

A dose of 10-15 mg/kg to be repeated (please see the table below).

– Do not give to your child more than 60 mg /kg presented in divided doses throughout 24 hours.

– Do not give to your child more frequently than every 4 hours.

– Do not give to your child more than four doses in any 24-hour period

– Do not give to your child for longer than 3 days without asking a doctor

Children aged 1 to 3 months:

A single dose of 10 - 15 mg/ kg for symptomatic relief of reaction due to vaccination.

If fever persists for more than 24 hours (4 doses) seek medical advice. This is to ensure that fever that may be due to a serious infection is quickly diagnosed.

For other indications, give only under medical advice.Not recommended in children under 1 month.

Do not give more than the stated dose.

If an excessive amount is taken a doctor should be contacted immediately even if the child feels well.

Age	Weight (kg)	Dose Vol (ml) *
1-3 months	5-6 kg	3.0 ml
3-4 months	6-7 kg	3.5 ml
4-6 months	7-8 kg	4.0 ml
6-8 months	8-9 kg	5.0 ml
8-12 months	9-10 kg	5.5 ml
1-2 years	10-12 kg	6.0 ml
2-3 years	12-14 kg	7.5 ml
3-4 years	14-16 kg	8.5 ml
4-5 years	16-18 kg	10 ml

* Dose may be chosen based on weight or age, use weight if you know it, otherwise use age.

– Do not exceed the stated dose.

– Use the smallest dose needed for the shortest period of time.

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 this medicine if the child is already taking any other prescription or non-prescription medicines containing paracetamol to treat pain, fever and symptoms of cold and flu or to aid sleep.
- Paracetamol overdose may cause liver failure which may require liver transplant or lead to 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.
- Too much paracetamol may cause serious harm to the liver.
- Patients with rare hereditary problems of fructose intolerance should not take this medicine as it contains Maltitol & Sorbitol liquid.
- This product contains Sodium ethyl parahydroxybenzoate – E215, Sodium methyl parahydroxybenzoate-E219, Sodium propyl parahydroxybenzoate- E217 which may cause allergic reactions (possibly delayed).
- Do not exceed the stated dose.
- Seek medical advice before giving the product if the child:

    1. Has a liver or kidney problem.
    2. Is underweight or malnourished .
    3. Has severe infection that may cause increased risk of metabolic acidosis. Signs of metabolic acidosis include: deep, rapid and difficult breathing, feeling sick (nausea and vomiting) and loss of appetite. Contact a doctor immediately if your child gets a combination of these symptoms.

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

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 colestyramine. The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

4.6 Pregnancy and lactation

This product is intended for use in children.
Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use. Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Adverse events of paracetamol 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, angiodema and Stevens Johnson syndrome/toxic epidermal necrolysis. Very rare cases of serious skin reactions have been reported.

Respiratory, thoracic and mediastinal disorders	Bronchospasm*
Hepatobiliary disorders	Hepatic dysfunction

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

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 EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

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.

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.
  Or
- Regularly consumes ethanol in excess of recommended amounts.
  Or
- Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms

Symptoms of paracetamol overdose in the first 24 hours are 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, haemorrhage,

hypoglycaemia, cerebral oedema and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Management

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

Paracetamol has analgesic and antipyretic actions. It is only a weak inhibitor of prostaglandin biosynthesis, although there is some evidence to suggest that it may be more effective against enzymes in the CNS than those in the periphery. This fact may partly account for its ability to reduce fever (a central action) and to induce analgesia.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. Concentration in plasma generally reaches a peak in 20-30 minutes; plasma half-life is 1-4 hours. Paracetamol is relatively uniformly distributed throughout most body fluids. Plasma binding is variable. Excretion is almost exclusively renal in the form of conjugates.

5.3 Preclinical safety data

Preclinical safety data on paracetamol in the literature have not revealed any pertinent and conclusive findings which are of relevance to the recommended dosage and use of the product and which have not been mentioned elsewhere in this Summary.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Malic Acid, Azorubine, Xanthan Gum, Maltitol Syrup, Strawberry Flavour, 70%

Sorbitol

Liquid Crystallising, Sodium ethyl parahydroxybenzoate, Sodium methyl parahydroxybenzoate, Sodium propyl parahydroxybenzoate, Sorbitol, Anhydrous Citric Acid, Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

To be stored below 30ºC

6.5 Nature and contents of container

Amber glass bottle (60 ml and 100 ml) fitted with white tamper-proof child-resistant closures. The bottle is packed into a cardboard carton accompanied by syringe and a patient information leaflet.

6.6 Special precautions for disposal

No Special requirements

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

Certificate No: 08000/08459/REN/2022

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Oct 23, 2022

10 DATE OF REVISION OF THE TEXT

August 2023