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.

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

Age	**Dose**
2 – 3 months • **Weighs over 4 kg** • **Was not premature (not born before 37 weeks)**	**One 2.5 mL spoonful (small end)** **If necessary, after 4-6 hours, give a second 2.5 mL spoonful**
• **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)
3 – 6 months	**One 2.5 mL spoonful (small end)**	**4 times**
6 – 24 months	**One 5 mL spoonful (large end)**	**4 times**
2 – 4 years	**One 5.0 mL spoonful (large end) and one 2.5 mL spoonful (small end)**	**4 times**
4 – 8 years	**Two 5 mL spoonfuls (large end)**	**4 times**
8 – 10 years	**Three 5 mL spoonfuls (large end)**	**4 times**
10 - 12 years	**Four 5 mL spoonfuls (large end)**	**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**

Method of administration

Panadol Baby and Infant Suspension is for oral administration only.

4.3 Contraindications

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.

Do not exceed the recommended dose.

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

If symptoms persist consult your doctor.

Keep out of the reach and sight of children.

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

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

The label should contain the following statements:

- Contains paracetamol.
- Do not give this medicine with any other paracetamol-containing product.
- For oral use only.
- Never give more medicine than shown in the table.
- Do not overfill the spoon.
- Always use the spoon 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 reach and sight of children.
- Immediate medical advice should be sought in the event of an overdose, even if the child seems well (label).
- Immediate medical advice should be sought in the event of an overdose, even if the child seems well, because of the risk of delayed, serious liver damage (leaflet).

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
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.

4.9 Overdose

Liver damage is possible in adults who have taken 10g or more of paracetamol. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

Risk Factors:

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 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. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol; however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24h from ingestion should be discussed with the NPIS or a liver unit.

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

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Malic acid, maltitol liquid, strawberry flavour L10055, nipasept sodium, hexacol carmoisine supra E122, xanthan gum, sorbitol solution, sorbitol powder, citric acid, purified water.

6.2 Incompatibilities

None

6.3 Shelf life

36 months

6.4 Special precautions for storage

To be stored below 30ºC

Do not freeze

6.5 Nature and contents of container

25ml, 100ml, 200ml and 1000ml amber glass bottles fitted with white clic-loc closures with PVC faced pulpboard wads or black bakelite screw caps

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

GlaxoSmithKline Consumer Healthcare (UK) Trading Limited,
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Brentford
Middlesex
TW8 9GS
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 44673/0088

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10/10/1990 / 09/06/2005

10 DATE OF REVISION OF THE TEXT

30/08/2016