SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PANADOL BABY

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml suspension contains:
Active ingredient: Paracetamol 120mg.
For excipients see section 6.1 List of excipients.

3. PHARMACEUTICAL FORM

Pink viscous liquid; crystals may present.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of pain from mild to moderate intensity and/or fever.

4.2 Posology and method of administration

For oral administration only.
PANADOL BABY is not recommended for children under the age of 2 months.
PANADOL BABY is indicated for children with a body mass from 4 to 42 kg (approximately up to 12 years).
The dosing depends on age and body mass of a child.
Approximate single doses, which are determined in accordance with the age and body mass of a child, are shown in the table below.
The recommended single dose of paracetamol is 10-15 mg/kg of body mass. 1ml of the drug contains 24mg of paracetamol. Give to a child every 4-6 hours, but no more than four doses in any 24 hour period. Minimum dosing interval: 4 hour

Body mass (kg)	**Age**	**Single dose (ml)**	**Maximum daily dose (ml)**
4-7	2-6 months	2,5	15
7-10	6 months - 1 year	2,5-5,0	18-25
10-12	1-2 years	5,0-7,5	25-30
12-16	2-4 years	7,5-10,0	30-40

16-19	4-5 years	10,0	40 -47
20-25	6-7 years	12,0	50-62
26-31	8-9 years	16,0	65-77
32-42	10-12 years	20,0	80-105

The range of maximum daily dose corresponds to the range of body weight, where lower values correspond to lower and larger values – to larger.

Maximum daily dosage is 60mg/kg presented in divided doses of 10 - 15 mg/kg throughout the 24 hour period.

The medicine can be taken in pure form or diluted in water, milk or fruit juice.

Systemic use of the drug avoids severe febrile conditions or changes in pain intensity.

Do not exceed the stated dose.

The lowest dose necessary to achieve efficacy should be used.

Maximum duration of continued use without medical advice: 3 days.

Should not be used with other paracetamol-containing products.

Renal impairment. In patients with renal impairment (creatinine clearance ≤ 10 ml/min) interval of taking the medication must be at least 8 hours.

Hepatic impairment. Patients who have been diagnosed with liver impairment must seek medical advice before taking the medication.

4.3 Contraindications

This product is contraindicated in patients with:

- a previous history of hypersensitivity to paracetamol or excipients;
- liver failure.

4.4 Special warnings and precautions for use

Contains paracetamol.

Children: Patients with moderate or severe renal or hepatic insufficiency should consult a doctor before taking the drug.

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.

Maximum recommended doses:
- children with body mass less than 37 kg: total dose of paracetamol must not exceed 80 mg/kg/day (see section 4.9 Overdose).
- children with body mass from 38 to 50 kg: total dose of paracetamol should not exceed 3 g/day (see section 4.9 Overdose).

PANADOL BABY contains sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine. Each 120mg/5 ml suspension contains sorbitol (E 420) at 666.5 mg per 5 ml suspension.
In patients with glutathione depleted states such as sepsis, the use of paracetamol may increase the risk of metabolic acidosis.

In children receiving paracetamol at a dose of 60 mg/kg/day, combination with another antipyretic is justified only if paracetamol is ineffective.
The composition of the drug includes a dye azorubin E122, which can cause allergic reactions. Due to the presence of parahydroxybenzoates (sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate, sodium ethyl parahydroxybenzoate), allergic reactions (including delayed ones) are possible.

If symptoms persist, medical advice must be sought.
Keep out of sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

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.
Therapy in terms of INR (international normalized ratio) should be regularly monitored. If necessary, the dose of the oral anticoagulant should be adjusted during treatment with paracetamol and after stopping use of paracetamol.
At abnormally high concentrations, paracetamol intake can affect blood glucose level's results through the glucose oxidase-peroxidase reaction.
The use of paracetamol can affect the results of the determination of blood urea by the method in which phosphotungstic acid is used.

4.6 Pregnancy and lactation

Fertility: No relevant data available.
Pregnancy: Animal and epidemiological studies have not identified any risk of embryo-foetal development or the fetotoxic effects of paracetamol. Thus, the use of the drug in therapeutic doses is possible during pregnancy.

Lactation: Human studies with paracetamol have not identified any risk to lactation or the breast-fed offspring. Paracetamol crosses the placental barrier and is excreted in breast milk. The use of the drug in therapeutic doses is possible during lactation.

4.7 Effects on ability to drive and use machines

Unlikely to cause an effect on ability to drive and use machines.

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/labeled dose and considered attributable are specified below by System Organ Class and frequency.

The following convention has been utilised for the classification of undesirable effects: very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <1/1000), 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.

Blood and lymphatic system disorders

Very rare: thrombocytopaenia

Immune system disorders

Very rare: anaphylaxis.

Cutaneous hypersensitivity reactions including, among others, skin rashes, angiodema, Stevens Johnson syndrome and Toxic Epidermal Necrolysis.

Respiratory, thoracic and mediastinal disorders

Very rare: Bronchospasm in patients sensitive to aspirin and other NSAIDs (non-steroidal anti-inflammatory drugs).

Hepatobiliary disorders

Very rare: Hepatic dysfunction.

Due to the presence of parabens (methyl and propyl parahydroxybenzoates), the development of urticaria is possible.

Reporting Adverse Reactions

If any adverse reaction occurred, it is recommended to consult a doctor. This recommendation applies to any possible adverse reaction, including those not listed in the package leaflet. You can also report adverse reactions to the information database on adverse reactions of drugs, including reports of drug inefficiencies. By reporting adverse reactions, you help get more information about the safety of the drug.

4.9 Overdose

Children: There is a risk of overdose in young children (therapeutic overdose or often accidental poisoning), which can be life threatening. There is also a risk of intoxication in elderly patients. Symptoms usually occur within the first 24 hours and include nausea, vomiting, anorexia, skin pallor, abdominal pain. Liver damage is possible in adults who have taken 10 g or more of paracetamol and in children who have taken over 150 mg/kg of body weight. Paracetamol overdose may cause complete irreversible liver necrosis, resulting in liver failure, metabolic acidosis and encephalopathy, which can lead to liver transplant, coma and death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity

12-48 hours after administration, an increase in the level of liver transaminases, lactate dehydrogenase and bilirubin may be observed, simultaneously with a decrease in the level of prothrombin.

The procedure for emergency medical care.

Immediate medical management is required in the event of overdose, even if symptoms of overdose are not present.

Blood sampling to determine the level of paracetamol in blood plasma.

Gastric lavage in case of oral administration of the drug.

Administration of N-acetylcysteine or methionine intravenously or orally as soon as possible within 10 hours after taking the drug may be required.

Symptomatic therapy.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other analgesics and antipyretics. Anilides. Paracetamol.
ATC code: N02BE01

5.1 Pharmacodynamic properties

Mechanism of Action

Paracetamol is an analgesic and antipyretic. Its mechanism of action is believed to include inhibition of prostaglandin synthesis, primarily within the central nervous system.
It blocks cyclooxygenase in the central nervous system, affecting the centers of pain and thermoregulation. Anti-inflammation effect is almost absent.

Pharmacodynamic Effects

The lack of peripheral prostaglandin inhibition confers important pharmacological properties such as the maintenance of the protective prostaglandins within the gastrointestinal tract. Paracetamol is, therefore, particularly suitable for: patients with a history of disease or patients taking concomitant medication, where peripheral prostaglandin inhibition would be undesirable (such as, for example, those with a history of gastrointestinal bleeding or the elderly).

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. Binding to plasma proteins is 15%. Concentration in plasma generally reaches a peak in 30-60 minutes. Paracetamol is relatively uniformly distributed throughout most body fluids.

It metabolizes mostly in liver with the formation of several metabolites. In newly-born children during the first days of life and in children aged 3-10 years the main metabolite of paracetamol is paracetamol sulphate, in children aged 12 years and above – conjugated glucuronide. Part of paracetamol (approximately 17%) undergoes hydroxylation with formation of active metabolites, which conjugated with glutathione. In deficiency of glutathione these metabolites may block the enzyme system of hepatocytes and develop necrosis.

Half-life of paracetamol when used at therapeutic doses is 2-3 hours.

When used at therapeutic doses 90-100% of ingested dose is excreted with urine during one day. The main part of the medicine is excreted after conjugation in liver. No more than 3% of ingested dose of paracetamol is excreted in unchanged form.

5.3 Preclinical safety data

Preclinical safety data on paracetamol in the literature have not revealed findings which are of relevance to the recommended dosage and use of the product.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Malic acid, azorubine E122, xanthan gum, maltitol syrup, strawberry flavour L10055, sorbitol, liquid (crystallizing) 70% w/v, sodium methyl parahydroxybenzoate, sodium ethyl parahydroxybenzoate, sodium propyl parahydroxybenzoate, sorbitol, anhydrous citric acid, purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months. Do not use after expiry date indicated on the package.

Shelf life after opening – 1 month.

6.4 Special precautions for storage

Store below 25°C. Protect from light. Do not freeze. Keep out of the sight and reach of children.

6.5 Nature and contents of container

Suspension 120mg/5ml in 100 ml dark glass bottles. 100 ml bottle is packed with syringe and patient information leaflet in a carton box.

6.6 Special precautions for disposal

Not applicable.

7. MANUFACTURER

Farmaclair, 440 Avenue du General de Gaulle, 14200 Herouville Saint Claire, France.

8. MARKETING AUTHORIZATION HOLDER

GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS, UK

9. MARKETING AUTHORIZATION NUMBER

15456/1

10. DATE OF REVISION OF THE TEXT

27.04.2020