Summary of Product Characteristics

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1. NAME OF THE MEDICINAL PRODUCT

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Paediatric Paracetamol oral Solution BP 120mg/5ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml solution contains:

Paracetamol BP…120mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Liquid orals (Oral solution)

Pink Coloured Solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Paediatric paracetamol oral solution BP 120mg/5ml is indicated for the treatment of mild to moderate pain, including headache, migraine, neuralgia, toothache, sore throat, period pains, aches and pains.

For the reduction of fever and to be used as an adjunctive treatment to relieve symptoms of cold and flu.

4.2 Posology and Method of administration

Posology

For the relief of fever after vaccinations at 2, 3 and 4 months One 2.5 mL spoonful (small end). This dose may be given up to 4 times a day starting at the time of vaccination. Do not give more than 4 doses in any 24 hour period. Leave at least 4 hours between doses. If your baby still needs this medicine two days after receiving the vaccine talk to your doctor or pharmacist.	
Age: 2 – 3 months	**Dose**
Pain and other causes of fever - if your baby weighs over 4 kg and was born after 37 weeks	One 2.5 mL spoonful (small end). If necessary, after 4-6 hours, give a second 2.5 mL dose

• Do not give to babies less than 2 months of age

• Leave at least 4 hours between doses

• Do not give more than 2 doses. This is to ensure that fever that may be due to a serious infection is quickly diagnosed. If your child is still feverish after two doses, 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		

4.3 Contraindications

Hypersensitivity to paracetamol and/or other constituents.

4.4 Special warnings and precautions for use

Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.

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 measuring cup.
- Always use the measuring cup 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.
- Do not store at temperature exceeding 30°C. Store in the original package.
- Keep all medicines 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 interact.

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 use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

4.6 Fertility, Pregnancy and Lactation

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

Not Known

4.8 Undesirable effects

Very rare cases of serious skin reactions have been reported. Adverse effects of paracetamol are rare but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these are not necessarily causally related to paracetamol.

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.

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4.9 Overdose

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 attention and any patient who had ingested around 7.5 g or more of paracetamol in the preceding 4 hours should undergo gastric lavage. Administration of oral methionine or intravenous N-acetylcysteine which may have a beneficial effect up to at least 48 hours after the overdose may be required. General supportive measures must be available.

Symptoms of paracetamol overdosage 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, coma and death. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Liver damage is possible in adults who have taken 10 g or more of paracetamol.

5.0 Pharmacological Properties

5.1 Pharmacodynamic Properties

Paracetamol has analgesic and anti-pyretic properties but no anti-inflammatory properties except at very high doses. Paracetamol inhibits prostaglandin synthesis, more centrally than peripherally.

5.2 Pharmacokinetic properties

Paracetamol is rapidly absorbed from the upper gastrointestinal tract after oral administration.

It is rapidly distributed throughout the body and is primarily metabolised in the liver.

About 85% is conjugated with glucuronide and sulphate and about 10% is conjugated with glutathione.

Excretion of the biotransformation products is via the kidney. The elimination half life is approximately 2-3 hours.

In overdose glucuronide pathways become saturated and excess paracetamol is metabolised via the glutathione pathway. Hepatic glutathione is rapidly depleted and an intermediate hydroxylamine metabolite accumulates and binds to liver proteins causing irreversible damage.

5.3 Preclinical safety data

None stated

6.0 Pharmaceutical particulars

6.1 List of excipients

Sucrose, Sodium Methyl Hydroxybenzoate, Sodium Propyl Hydroxybenzoate, Sodium Benzoate, Disodium Edetate, Colour Erythrosine Supra, Citric acid monohydrate, Propylene Glycol, Liquid Sorbitol (non crystallizing), Mixed Fruit Flavour (liquid), Purified Water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at temperature not exceeding 30°C in a dry place. Protect from light.

6.5 Nature and contents of container

60 ml Amber coloured PET bottle

6.6 Special precautions for disposal and other handling

No special requirements

7. Marketing Authorisation Holder

MEDICAMEN BIOTECH LIMITED

SP-1192 A & B, Phase-IV,
Industrial Area, Bhiwadi-301019,
Distt Alwar, Rajasthan India

8. Number(s) in the national register of finished pharmaceutical products

Certificate No: 1489/NMR/LD

9. Date of first authorisation/renewal of the authorisation

Jan 30, 2013

10. Date of revision of the text

August 2023