

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Medinol Under 6 Paracetamol Oral Suspension 120mg/5ml.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml suspension contains 120mg Paracetamol.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Oral Suspension.

A grey/white viscous thixotropic liquid oral suspension with a strawberry odour and taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an analgesic for the treatment of mild to moderate pain and as an anti-pyretic.

4.2 Posology and method of administration

Route of administration

Oral.

Age	Dose
For post-vaccination fever for babies aged between 2 – 3 months	One 2.5 mL spoonful (small end) If necessary, after 4-6 hours, give a second 2.5 mL dose
<ul style="list-style-type: none">• 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 – 6 years	Two 5 mL spoonfuls (large end)	4 times
<ul style="list-style-type: none">• 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

The following medical advice should be given:

- It is important to **shake the bottle** for at least 10 seconds before use.
- Do not give with any other paracetamol-containing products
- 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 before taking this product.
- 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.
- Keep out of the reach and sight of children.
- If pain or fever persists for more than 3 days consult a doctor.
- Prolonged use without medical supervision may be harmful.
- Do not exceed the recommended dose.
- In cases of accidental overdose seek medical attention immediately due to the risk of delayed serious liver damage.

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

This product contains propylhydroxybenzoate (E216) and methylhydroxybenzoate (E218) which may cause allergic reactions (possibly delayed)

4.5 Interaction with other medicinal products and other forms of interaction

Cholestyramine may reduce absorption of paracetamol. Metoclopramide and domperidone may accelerate absorption of paracetamol. Alcohol, barbiturates, anti-convulsants and tricyclic anti-depressants may increase the hepatotoxicity of paracetamol particularly after an overdose. The anti-coagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding.

4.6 Fertility, pregnancy and lactation

There is epidemiological evidence of the safety of paracetamol in human pregnancy. Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast-feeding. This product may, therefore, be taken during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Haematological reactions have been reported. Skin rashes and other allergic reactions occur occasionally. Most reports of adverse reactions to paracetamol relate to overdosage with the drug.

4.9 Overdose

An overdose should be treated as soon as possible (within 12 hours) as liver damage from an overdose does not become apparent for 1-6 hours after ingestion. Initial symptoms include pallor, nausea, vomiting, anorexia and abdominal pain.

Treatment

After gastric lavage a suitable antidote such as acetylcysteine or methionine should be given. Acetylcysteine is given by intravenous infusion in an initial dose of 150mg/kg body weight over 15 minutes, followed by 50mg/kg over 4 hours and then by 100mg/kg over the next 16 hours. Alternatively, methionine 2.5g may be given by mouth every four hours to a total of 4 doses. The blood paracetamol levels should be monitored to determine whether further therapy is necessary.

In severe poisoning, hepatic failure may progress to encephalopathy, coma and death. Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of early symptoms, patients should be referred to hospital urgently for medical attention. Any patient who has ingested around 7.5mg or more of paracetamol in the preceding 4 hours should undergo gastric lavage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Analgesic/anti-pyretic.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tragacanth
Maltitol Solution (E965)
Methylhydroxybenzoate (E218)
Propylhydroxybenzoate (E216)
Sodium Saccharin
Sodium Cyclamate
Strawberry Flavour PFW 500253E
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf life

Three years.

6.4 Special precautions for storage

Do not store above 25oC. Do not refrigerate.

6.5 Nature and contents of container

Amber glass sirop or winchester bottle (Ph. Eur. Type II) with a tamper evident polypropylene HDPE cap with unfaced closed cell expanded polyethylene wad, containing 100 ml and 200 ml of product into an outer carton containing a 5 ml spoon with a 2.5 ml graduation.

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

Cupal Limited,
Tubiton House,
Oldham, OL1 3HS,
U.K.

8 MARKETING AUTHORISATION NUMBER

PA 0258/015/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th November 1988

Date of last renewal: 16th November 2003

10 DATE OF REVISION OF THE TEXT

December 2013