1 JUNIOR PARAPAED, SIX PLUS PARAPAED

Paracetamol suspension 120mg/5ml and 250mg/5ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Junior Parapaed

Each 5ml spoonful contains Paracetamol BP 120mg. Pink suspension with cherry odour and taste.

Six Plus Parapaed

Each 5ml spoonful contains Paracetamol BP 250mg. Yellow suspension with orange odour and taste.

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Oral suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of mild to moderate pain and as an anti-pyretic. Used for the relief of pain and feverishness associated with teething, toothache, headache, colds, flu and post-immunisation pyrexia.

4.2 Dose and method of administration

Junior Parapaed

Children 6 – 12 years: two to four 5ml spoonfuls
1 – 6 years: one to two 5ml spoonfuls.
3 months - 1 year: Half to one 5ml spoonful.
Under 3 months: a 2.5ml spoonful is suitable for babies who develop fever following vaccination at 2 months. In all other cases use only under medical supervision.

Repeat dose every 4 – 6 hours as required up to a maximum of 4 doses in 24 hours.

Six Plus Parapaed

Adults: two to four 5ml spoonfuls
Children: 6 – 12 years: One to two 5ml spoonfuls
1 – 6 years: Half to one 5ml spoonfuls
Under 1 year: not recommended

Repeat dose every 4 – 6 hours as required up to a maximum of 4 doses in 24 hours.

4.3 Contraindications

Hypersensitivity to Paracetamol or any of the excipients.

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.

Do not give with any other Paracetamol-containing products.

Immediate medical advice should be sought in the event of overdose, even if the child seems well.

4.5 Interaction with other medicines and other forms of interaction

Drugs, which induce hepatic microsomal enzymes such as alcohol. Concomitant barbiturates and tricyclic antidepressants may increase the hepatoxicity of Paracetamol particularly after overdose. Anti-convulsant or oral steroid contraceptives have the ability to reduce serum levels of Paracetamol by liver enzyme induction. The speed of absorption of Paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine. The anti-coagulant 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

Use in Pregnancy (Category A)

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.

Use in Lactation

Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data does not contraindicate breast-feeding.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

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 were not necessarily causally related to Paracetamol. With prolonged use or overdosage, hepatic necrosis, acute pancreatitis and nephrotoxicity have been reported.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/

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 medical attention and any patient who had ingested around 7.5g 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 10g or more of Paracetamol.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Paracetamol is an antipyretic analgesic. The mechanism of action is probably similar to that of aspirin and dependent on the inhibition of prostaglandin synthesis. This inhibition appears, however, to be on a selective basis.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastro-intestinal tract. The concentration in plasma reaches a peak in 30 to 60 minutes and the half-life in plasma is 1 to 4 hours after therapeutic doses. Paracetamol is relatively uniformly distributed throughout most body fluids. Binding of the drug to plasma proteins is variable; 20 to 50 % may be bound at the concentrations encountered during acute intoxication. Following therapeutic doses 90 to 100% of the drug may be recovered in the urine within the first day. However, practically no Paracetamol is excreted unchanged, and the bulk is excreted after hepatic conjugation.

5.3 Preclinical safety data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol (96%) BP
Sorbitan Monooleate BP
Glycerol BP
Magnesium Aluminium Silicate USNF
Hydrogenated Glucose Syrup HSE
Saccharin Sodium BP
Xanthan Gum USNF
Amaranth HSE
Sodium Benzoate BP
Citric Acid (monohydrate) BP
Polysorbate 80 BP
Cherry Flavour HSE (Junior Parapaed) or Orange Flavour 6902 (Six Plus Parapaed)
Purified water to volume

6.2 Incompatibilities
None.

6.3 Shelf life
60 months

6.4 Special precautions for storage
Store at or below 25°C. Store in the original container.

6.5 Nature and contents of container
High density polyethylene bottle with tamper evident plastic cap. Type III Amber glass bottle.
Pack Sizes
Junior Parapaed: 100ml, 200ml, 500ml, 1 Litre.
Six Plus Parapaed: 100ml, 200ml, 500ml, 1 Litre.

6.6 Special precautions for disposal
None.

7 MEDICINE SCHEDULE

Pharmacy only medicine.

8 SPONSOR

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SUMMARY TABLE OF CHANGES

Date	**Section(s) Changed**	**Change (s)**
October 2018	All	Reformat consistent with new Medsafe Data Sheet Template.