NEW ZEALAND DATA SHEET

1. PRODUCT NAME

Junior Parapaed

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of suspension contains Paracetamol 120 mg.

Excipients with known effect:

Ethanol and Liquid Maltitol.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension

Pink suspension with cherry odour and taste.

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 fever.

4.2 Dose and method of administration

For oral administration only

It is important to shake the bottle well before use.

For children aged more than 6 years, use SIX PLUS Parapaed

Age	Body weight (kg)	Volume to be taken
1 - 2 months	4 - 5	2 mL
3 - 6 months	6 - 7	3.5 mL
7 - 11 months	8 - 9	5 mL
12 - 23 months	10 - 12	6 mL
2 years	13 - 14	8 mL
3 years	15 - 16	9.5 mL
4 years	17 - 18	10.5 mL
5 years	19 - 20	12 mL
6 years	21 - 22	13 mL

Do not exceed the stated dose. Dose every four to six hours when required, no more than four doses in 24 hours. The lowest dose necessary to achieve efficacy should be used for the shortest duration of treatment. Should not be used with other paracetamol-containing products.

Minimum dosing interval: 4 hours.

Use the dose for your child's weight. Only dose for age if you don't know your child's weight.

4.3 Contraindications

Hypersensitivity to paracetamol and/or any of the excipients.

Patients with severe hepatic dysfunction.

4.4 Special warnings and precautions for use

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

Contains paracetamol. 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 may require liver transplant or lead to death.

Renal or Hepatic impairment:

Paracetamol should be used with caution in patients with underlying liver disease increases the risk of paracetamol-related liver damage.

Paracetamol should be used with caution in patients with impaired kidney function. Administration of paracetamol to patients with moderate to severe renal impairment may result in accumulation of paracetamol conjugates.

Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication. The restrictions related to the use of paracetamol products in patients with liver or kidney impairment are primarily a consequence of the paracetamol content of the drug.

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.

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, are chronic heavy users of alcohol or have sepsis.

Glutathione depleted states:

In patients with glutathione depleted states the use of paracetamol may increase the risk of metabolic acidosis.

Coadministration with flucloxacillin:

Caution is advised if paracetamol is administered concomitantly with flucloxacillin due to increased risk of high anion gap metabolic acidosis (HAGMA), particularly in patients with severe renal impairment, sepsis, malnutrition, and other sources of glutathione deficiency (e.g. chronic

alcoholism), as well as those using maximum daily doses of paracetamol. Close monitoring, including measurement of urinary 5-oxoproline, is recommended.

This product contains 39 g maltitol per 52 mL (maximum recommended daily dose in 6 years old). Products containing maltitol may have a laxative effect or cause diarrhoea.

Children and adolescents use

Do not give/take this medicine for longer than 48 hours at a time unless advised by a healthcare professional. Use the dose for your child's weight. Only dose for age if you don't know your child's weight.

Adults use
Do not take this medicine for longer than a few days at a time unless advised by a healthcare professional.

4.5 Interaction with other medicines and other forms of interaction

The risk of paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce liver microsomal enzymes such as alcohol and anticonvulsant drugs.

Paracetamol excretion may be affected, and plasma concentrations altered when given with probenecid.

Paracetamol absorption is increased by substances that increase gastric emptying, e.g. metoclopramide

Paracetamol absorption is decreased by substances that decrease gastric emptying, e.g. propantheline, antidepressants with anticholinergic properties and narcotic analgesics.

Cholestyramine reduces the absorption of paracetamol if given within one hour of paracetamol.

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. Anticoagulant dosage may require reduction if Paracetamol medication is prolonged.

Paracetamol may increase chloramphenicol concentrations.

Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis, especially in patients with risks factors (see section 4.4).

4.6 Fertility, pregnancy, and lactation

Use in pregnancy

As with the use of any medicine during pregnancy, pregnant women should seek medical advice before taking paracetamol.

Pregnancy Category A

Paracetamol has been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.

Use in lactation

Paracetamol is excreted in breastmilk but not in a clinically significant amount at recommended dosages. Available published data do not contraindicate breast-feeding.

4.7 Effects on ability to drive and use machines

Paracetamol is unlikely to cause an effect on the ability to drive or use machinery.

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/labelled dose and considered attributable are tabulated 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 to <1/10
Uncommon	≥1/1,000 to <1/100
Rare	≥1/10,000 to <1/1,000
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.

Body System	**Undesirable Effect**	**Frequency**
Blood and lymphatic system disorders	Thrombocytopenia	Very rare
Immune System Disorders	Anaphylaxis Cutaneous hypersensitivity reactions including, among others, skin rashes, angioedema, Stevens Johnson syndrome and Toxic Epidermal Necrolysis	Very rare
Respiratory, thoracic and mediastinal disorders	Bronchospasm, especially in patients sensitive to aspirin and other NSAIDs	Very rare
Hepatobiliary disorders	Hepatic dysfunction	Very rare

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://pophealth.my.site.com/carmreportnz/s/.

4.9 Overdose

Experience following overdose with paracetamol indicates that the clinical signs of liver injury occur usually after 24 to 48 hours and have peaked after 4 to 6 days.

Paracetamol overdose may cause liver failure which may require liver transplant or lead to death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity. Immediate medical management is required in the event of an overdose, even if the symptoms of overdose are not present.

If an overdose is taken or suspected, contact the Poisons Information Centre immediately for advice (0800764766), or the patient should go to the nearest hospital straightaway. This should be done even if they feel well because of the risk of delayed, serious liver damage.

Administration of N-acetylcysteine may be required.

In cooperative adults, activated charcoal may reduce absorption of the medicine if given within one hour after ingestion.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other Analgesics and Antipyretics (Anilides)

ATC Code: N02 BE01.

The mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (CNS) and, to a lesser extent, through a peripheral action by blocking pain impulse generation. The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitise pain receptors to mechanical or chemical stimulation.

Paracetamol probably produces antipyresis by acting centrally on the hypothalamic heat regulating centre to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

5.2 Pharmacokinetic properties

Oral absorption is rapid and almost complete, it may be decreased if Paracetamol is taken following a high carbohydrate meal.

There is no significant protein binding with doses producing plasma concentrations below 60mcg (µg)/ml but may reach moderate levels with high or toxic doses.

Approximately 90 - 95% of a dose is metabolised in the liver, primarily by conjugation with glucuronic acid, sulphuric acid, and cysteine. An intermediate metabolite, which may accumulate in

overdosage after primary metabolic pathways become saturated, is hepatotoxic and possibly nephrotoxic.

Half-life is 1 to 4 hours; does not change with renal failure but may be prolonged in acute overdosage, in some forms of hepatic disease, in the elderly, and in the neonate; may be somewhat shortened in children.

Time to peak concentration, 0.5 - 2 hours; peak plasma concentrations, 5 - 20mcg (µg)/ml (with doses up to 650mg); time to peak effect, 1- 3 hours; duration of action, 3- 4 hours.

Elimination is by the renal route, as metabolites, primarily conjugates, 3% of a dose may be excreted unchanged.

Peak concentrations of 10 - 15mcg(µg)/ml have been measured in breast milk, 1 - 2 hours following maternal ingestion of a single 650mg dose. Half-life in breast milk is 1.35 - 3.5 hours.

5.3 Preclinical safety data

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Ethanol (96%)
- Sorbitan monooleate
- Glycerol
- Magnesium aluminium silicate
- Hydrogenated glucose syrup (liquid maltitol)
- Saccharin sodium
- Xanthan gum
- Sodium benzoate
- Citric acid monohydrate
- Polysorbate 80
- Amaranth
- Cherry flavour
- Purified water.

6.2 Incompatibilities

None Known

6.3 Shelf life

60 months

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Pack of 100 mL - Amber glass bottles with pilfer proof screw caps.
Pack of 200 mL - Amber glass bottles with pilfer proof screw caps.
Pack of 500 mL - High density polyethylene bottles with tamper evident plastic cap.
Pack of 1L - High density polyethylene bottles with tamper evident plastic cap.

6.6 Special precautions for disposal

No special requirements

7. MEDICINE SCHEDULE

Pack of 100mL and 200 mL – Pharmacy only medicine

Pack of 500mL and 1 L- Pharmacist only medicine.

8. SPONSOR

AFT Pharmaceuticals Limited

PO Box 33-203

Takapuna Auckland 0740

Phone: 0800 423 823

9. DATE OF FIRST APPROVAL

29 May 2003

10. DATE OF REVISION OF THE TEXT

16 July 2024