Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

PARAFAST ET JUNIOR 160mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Effervescent Tablet Contains
Paracetamol BP160 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Effervescent Tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of mild to moderate pain, including headache, migraine, neuralgia, toothache, pain in teething, sore throat, aches and pains Symptomatic relief of influenza, feverishness, feverish colds.

4.2 Posology and method of administration

Children 3-12 months: one tablet every four hours.

Children 1 year – under 6 years: one to two tablet every four hours Children 6 years – 12 years: 2 to 4 tablet every four hours
Dosage for children under 3 months is at Physicians discretion. Not more than 4 doses should be administered in any 24-hour period.

Direction for Use:

Dissolve the tablet in a glass of water(approx..200ml) Drink as soon as the tablet dissolves. Do not chew or swallow these tablets.

4.3 Contraindications

Hypersensitivity to Paracetamol or excipients present in the formulation listed under 6.1

4.4 Special warnings and precautions for use

Use with caution in patients with Hepatic or Renal Dysfunction or Diabetes. Paracetamol should also be given with care to patients asking other drugs that effect the liver. Occasionally malnourished patients may be more sensitive to the toxic effects of Paracetamol.

4.5 Interaction with other medicinal products and other forms of interaction

Drugs, which induce hepatic microsmal enzymes such as Alcohol, Barbiturates and Tricyclic Antidepressants, may increase the hepatotoxicity of Paracetamol particularly after overdosage. Where Paracetamol is taken regularly or in high doses and Oral Anticoagulants such as Warfarin are administered concurrently, potentiation of the oral Anticoagulant may occur.

4.6 Fertility, Pregnancy and lactation

There is an epidemiological evidence of the safety of Paracetamol in pregnancy. Smaller effective doses should be used. There is no evidence of harm where Paracetamol is or has been taken during breastfeeding. However, in cases where Paracetamol has been taken by nursing mothers, significant amounts have been found in breast milk.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Adverse reactions associated with paracetamol identified from historical clinical trial data were infrequent and based on limited patient exposure. Accordingly, adverse reactions reported from extensive post-marketing experience at therapeutic/labelled doses and considered attributable to paracetamol are presented below by System Organ Class (SOC) and frequency.
Frequency categories: very rare (may affect up to 1 in 10,000 people) and not known (frequency cannot be estimated from available data).

System Organ Class	Undesirable Effect	Frequency
Blood and lymphatic system disorders	Thrombocytopenia; agranulocytosis	Very rare
Immune system disorders	Anaphylaxis; cutaneous hypersensitivity reactions, including skin rashes and angioedema	Very rare
Respiratory, thoracic and mediastinal	Bronchospasm*	Very rare

disorders		
Hepatobiliary disorders	Hepatic dysfunction	Very rare
Skin and subcutaneous tissue disorders	Serious skin reactions	Very rare
Metabolism and nutrition disorders	High anion gap metabolic acidosis	Not known

* Cases of bronchospasm have been reported with paracetamol, but these are more likely to occur in patients with asthma who are sensitive to aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs).

Description of Selected Adverse Reactions

High anion gap metabolic acidosis:

Cases of high anion gap metabolic acidosis due to pyroglutamic acidosis have been observed in patients receiving paracetamol who have relevant risk factors. Pyroglutamic acidosis may occur as a consequence of reduced glutathione levels in these patients.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

Over dosage should be treated promptly by gastric lavage followed by I.V.N Acetylcysteine or oral Methionine since liver Damage following over dosage does not become apparent for 1 t 6 days after ingestion. Initial mild symptoms consist of Nausea, Vomiting and Pallor. Measurements of the blood Paracetamol level and the time elapsed since ingestion is important in order to determine whether further therapy with N-Acetylcysteine is necessary. The hepatic changes produced by over dosage of Paracetamol result from the accumulation of highly reactive intermediated metabolites and hepatocytes.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Analgesic and
Antipyretic ATC code: N02BE01

Paracetamol has analgesic and antipyretic effects but has only weak anti-inflammatory effects. These actions are considered to be due to inhibition of the Biosynthesis of Prostaglandins.

5.2 Pharmacokinetic properties

Paracetamol is readily absorbed from the gastro-intestinal tract with peak plasma concentrations occurring about 30minutes to 2 hours after ingestion. It is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged Paracetamol.

The elimination half-life varies from 1-4 hours. Plasma protein binding is negligible at usual therapeutic concentrations but increase with increasing concentrations. A minor hyroxylated metabolite, which is usually produced in very small amounts by mixed function, oxidises in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following Paracetamol over dosage and cause liver damage. Particularly no Paracetamol is excreted unchanged, and the bulk is excreted after hepatic conjugation with glucuronic acid (about 60%) sulphuric acid (about 35%) or cysteine (about 3%) Children have less capacity for glucuronidation of the dugs than do adults. When high doses are ingested Paracetamol undergoes N-Hydroxylation t form (for further details see product licence file).

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid anhydrous, Sodium saccharine, PVP K 30, FD&C Red No. 40, Sodium Bicarbonate, Simeticone, Polysorbate 80, Sucralose, Sodium benzoate, and Strawberry flavour

6.2 Incompatibilities

None stated.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

4 Tablets are packed in an aluminium strips: 4 such strips are packed in a printed carton with pack insert

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORIZATION HOLDER

HighChem Marketing Ltd.

Manufacturing site:

Vovantis Laboratories Private Limited
Survey no. 546/1/1,
Opp. Ranoli Railway station,
Near GACL plant, Ranoli,
Vadodara, Gujarat - 391 350,
India.

8 MARKETING AUTHORISATION NUMBER(S)

H2025/CTD10812/23911

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14 July 2025

10 DATE OF REVISION OF THE TEXT

24/08/2026