AVPARA 500
(Paracetamol Tablets BP 500mg)

Summary of Product Characteristics

1. Name of the medicinal product

AVPARA 500 (Paracetamol Tablets BP 500mg)

2. Qualitative and Quantitative composition

Each uncoated tablet contains 500 mg of Paracetamol BP

3. Pharmaceutical form

White coloured round flat, bevelled edges uncoated tablets having embossed "PARA&500" with single breakline on one side and plain on another side

4. Clinical Particulars:

4.1 Therapeutic indications

A mild analgesic and antipyretic, recommended for the treatment of most painful and febrile conditions, for example, headache including migraine and tension headaches, toothache, backache, rheumatic and muscle pains, dysmenorrhoea, sore throat, and for relieving the fever, aches and pains of colds and flu. Also recommended for the symptomatic relief of pain due to non-serious arthritis.

4.2 Posology and method of administration

Adults, the elderly and children 16 years and over: One or two tablets to be taken every four to six hours, when necessary, up to four times daily. Maximum dose of 8 tablets in 24 hours. Children 10 - 15 years: One tablet to be taken every four to six hours, when necessary to a maximum of four doses in 24 hours. Not suitable for children under 10 years of age. Children should not be given tablets for more than 3 days without consulting a doctor. These doses should not be repeated more frequently than every four to six hours nor should more than 4 doses be given in any 24 hour period.

Method of administration

Paracetamol tablets to be administered orally only.

4.3 Contraindications

Hypersensitivity to paracetamol or any of the other constituents.

4.4 Special warnings and precautions for use

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

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.

Patients should be advised to consult their doctor if their headaches become persistent.
Patients should be advised not to take other paracetamol-containing products concurrently.
Patients should be advised to consult a doctor if they suffer from non-serious arthritis and need to take painkillers every day.
If symptoms persist consult your doctor. Keep medicines out of the sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction
The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by colestyramine. 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.
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 risk factors.

4.6 Pregnancy and Breast-feeding
Pregnancy
A large amount of data on pregnant women indicates neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.
Breast-feeding
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
None Stated.

4.8 Undesirable effects
Adverse events of paracetamol 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 class. Due to limited clinical trial data, the frequency of these adverse events is not known (cannot be estimated from available data), but post marketing experience indicates that adverse reactions to paracetamol are rare and serious reactions are very rare.
Post marketing data

Body System	**Undesirable effect**

Blood and lymphatic system disorders	Thrombocytopenia Agranulocytosis
Immune system disorders	Anaphylaxis Cutaneous hypersensitivity reactions including skin rashes and angiodema
Respiratory, thoracic and mediastinal disorders	Bronchospasm*
Hepatobiliary disorders	Hepatic dysfunction

***** There have been cases of bronchospasm with paracetamol, but these are more likely in
asthmatics sensitive to aspirin or other NSAIDs.
Very rare cases of serious skin reactions have been reported.

- **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. Healthcare professionals are asked to report any suspected adverse reactions to National Regulatory Agents

4.9 Overdose
Liver damage is possible in adults who have taken 10g or more of paracetamol. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors
Risk factors
If the patient:
A. Is on long term treatment with carbamazepine, phenobarbital, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes Or
B. Regularly consumes ethanol in excess of recommended amounts.
Or
C. Is likely to be glutathione deplete e.g., eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.
Symptoms
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, haemorrhage, hypoglycaemia, cerebral oedema, and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.
Management

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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. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage.
Management should be in accordance with established treatment guidelines, see BNF overdose section. Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable).
Treatment with Nacetylcysteine may be used up to 24 hours after ingestion of paracetamol, however, the maximum protective effect is obtained up to 8 hours post ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24hrs from ingestion should be discussed with the NPIS or a liver unit.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacodynamic group: Other analgesics and antipyretics, Anilids.
ATC Code: N02BE01
Paracetamol is an antipyretic analgesic. The mechanism of action is probably similar to that of aspirin and dependant 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 peak plasma concentrations occurring 30 minutes to 60 minutes and the plasma half-life 1-4 hours after therapeutic doses. Paracetamol is relatively uniformly distributed throughout most body fluids. Plasma protein binding is variable; 20 to 30% 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

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

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Sr. No.	Excipients
1.	STARCH
2.	DI CALCIUM PHOSPHATE
3.	METHYL PARABEN
4.	PROPYL PARABEN
5.	STARCH
6.	PVPK-30
7.	GELATIN
8.	TALC
9.	MAGNESIUM STEARATE
10.	SODIUM STARCH GLYCOLATE
11.	SODIUM LAURYL SULPHATE
12.	COLLOIDAL SILICON DIOXIDE

6.2 Incompatibilities
None Known

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store in a cool & dry place. Protect from light

6.5 Nature and contents of container
1 ALU PVC Blister of 10 Tablets, such 10 Blister packed in Printed Carton with Insert.

6.6 Special precautions for disposal and other handling
No special requirements

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURER
Marketing Authorisation Holder:
Aveo Pharmaceuticals Pvt. Ltd.
Plot No. C/13, Tarapur Industries area, MIDC,
Boisar, Palghar-401 506, Maharashtra, India.

MANUFACTURER
ZAIN PHARMA LTD.
Plot No: 209/13741, Colchester Park,
Go-Down No.1, 2, 3, Off Mombasa Road,
Behind Nice and Lovely House,
P.O. Box: 100167-00101, Nairobi, Kenya

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8. Marketing Authorization Number: CTD12448

9. Date of First <Registration> / Renewal of The <Registration>
01.06.2026

10. Date of Revision of the Text: 20/04/2026