PIARON EVT
Paracetamol Effervescent Tablets BP 500 mg

COMPOSITION:

Each effervescent tablet Contains:
Paracetamol BP 500 mg

Excipients:
Citric acid (anhydrous Powder Grade), Sorbitol Powder, Dimethicone, Aspartame, Povidone, Sodium Bicarbonate, Anhydrous Sodium Carbonate, Sodium Lauryl Sulphate, Purified water.

PRODUCT DESCRIPTION:

White to off White, round shape, bevelled edge tablet, plain on both sides.

Slightly opalescent solution appears after dissolving the tablet in water.

PHARMACOLOGICAL PROPERTIES:

Pharmacotherapeutic group: Other analgesics and antipyretics
ATC code: N02BE01.

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.

Pharmacokinetic Properties

Paracetamol is rapidly and almost completely absorbed from the gastro-intestinal tract. Concentration in plasma reaches a peak in 30-60 minutes. Plasma half-life is 1-4 hours. Paracetamol is relatively uniformly distributed throughout most body fluids. Plasma protein binding is variable. Excretion is almost exclusively renal, in the form of conjugated metabolites.

INDICATIONS:

Paracetamol is an analgesic and an antipyretic.
a. Treatment of mild-to-moderate pain including: Headache, Migraine, Muscle ache, Dysmennorhoea, Sore throat, Musculoskeletal pain, Fever and pain after vaccination, Pain after dental procedures / tooth extraction, Toothache, Pain of osteoarthritis.
b. Relief of fever

DOSAGE & MODE OF ADMINISTRATION

- Do not exceed the recommended dosage
- The lowest effective dose and the shortest duration of treatment should be used.
- Oral intake only
- Make sure you don’t take it more often than every 4 hours.
- Maximum daily dose: 4000 mg paracetamol (8 tablets)

Adults (including the elderly) and children aged 12 years and over:
1 to 2 tablets (500 mg to 1000 mg paracetamol), dissolved in at least half a tumbler of water every 4 to 6 hours as required.
Children 9 to 11 years:
Take 1 tablet (500 mg paracetamol), dissolved in half a glass of water.
Make sure your child does not take more than 4 doses in a 24 hour period.
If the pain lasts more than 3 days, please see a doctor.
The maximum daily dose based on body weight is 60mg/kg of paracetamol over a 24-hour period, in divided doses.

Children under 9 years: Not recommended for children under the age of 9 years.

Renal damage:
Patients with kidney disorder must seek medical advice before taking this medicine. Restrictions that related to the use of paracetamol products in patients with kidney disorders is a consequence of paracetamol content in the medicine.

Liver damage:
Patients with liver disorders must seek medical advice before taking this medicine. Related restrictions with the use of paracetamol products in patients with liver disorders is a consequence of the content of paracetamol in medication.

CONTRAINDICATIONS:
Hypersensitivity to the active substance or to any of the excipients

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

Allergy alert: Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

WARNING: This preparation contains **PARACETAMOL.** Do not take any other paracetamol containing medicines at the same time.

The concomitant use with other products containing paracetamol may lead to an overdose. Paracetamol overdose may cause liver failure which can lead to liver transplant or death.

Do not exceed the stated dose.
If symptoms persist, consult your doctor. Prolonged use except under medical supervision may be harmful. This product should only be used when clearly necessary.

Cases of paracetamol induced hepatotoxicity, including fatal cases, have been reported in patients taking paracetamol at doses within the therapeutic range. These cases were reported in patients with one or more risk factors for hepatotoxicity including low body weight (<50 Kg), renal and hepatic

impairment, chronic alcoholism, concomitant intake of hepatotoxic drugs, sepsis and in acute and chronic malnutrition (low reserves of hepatic glutathione).

Paracetamol should be administered with caution to patients with these risk factors.
Caution in patients with glutathione depleted states such as sepsis; the use of paracetamol may increase the risk of metabolic acidosis.
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.

Each Piaron Evt Tablet contains Aspartame at 59.39 mg per tablet. **WARNING**: Unsuitable for phenylketonurics.
Each Piaron Evt Tablet contains Sodium bicarbonate at 1500 mg per tablet and Anhydrous sodium carbonate at 20 mg per tablet. To be taken into consideration by patients on a controlled sodium diet.
Each Piaron Evt Tablet contains Sorbitol powder (E420) at 50 mg per tablet. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

Keep out of the sight and reach of children.

PREGNANCY AND LACTATION:

Pregnancy

A large amount of data on pregnant women indicate 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. However, the level of paracetamol present is not considered to be harmful.
Available published data do not contraindicate breastfeeding.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

None stated.

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 risks factors.

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 information below lists reported adverse reactions, ranked using the following frequency classification:

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 the 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 skin rashes, angioedema, Stevens Johnson Syndrome/Toxic Epidermal Necrolysis have been reported. Very rare cases of serious skin reactions have been reported.	Very rare
Respiratory, thoracic and mediastinal disorders	Bronchospasm in patients	Very rare
Hepatobiliary disorders	Hepatic dysfunction	Very rare

Reporting of suspected adverse reactions
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website *npra.gov.my* [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

OVERDOSE AND TREATMENT:

Symptoms and signs
Paracetamol overdose may cause liver failure which can lead to liver transplant or death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity.
There is a risk of poisoning with paracetamol particularly in elderly subjects, young children, patients with liver disease, cases of chronic alcoholism and in patients with chronic malnutrition. Overdosing may be fatal in these cases.
Symptoms generally appear within the first 24 hours and may comprise: nausea, vomiting, anorexia, pallor, and abdominal pain, or patients may be asymptomatic.
Overdose of paracetamol in a single administration in adults or in children can cause liver cell necrosis likely to induce complete and irreversible necrosis, resulting in hepatocellular insufficiency, metabolic acidosis and encephalopathy which may lead to coma and death. Simultaneously, increased

levels of hepatic transaminases (AST, ALT), lactate dehydrogenase and bilirubin are observed together with increased prothrombin levels that may appear 12 to 48 hours after administration.
Liver damage is likely in adults who have taken more than the recommended amounts of paracetamol. It is considered that excess quantities of toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested), become irreversibly bound to liver tissue.
Some patients may be at increased risk of liver damage from paracetamol toxicity.
Risk Factors include: If the patient;

- Is on long-term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.
- Regularly consumes ethanol in excess of recommended amounts
- Is likely to be glutathione depleted e.g. eating disorders, cystic fibrosis, HIV infection, starvation, Cachexia.

Emergency Procedure:
Immediate transfer to hospital.
Blood sampling to determine initial paracetamol plasma concentration. In the case of a single acute overdose, paracetamol plasma concentration should be measured 4 hours post ingestion.
Administration of activated charcoal should be considered if >150mg/kg paracetamol has been taken within 1 hour.
The antidote N-acetylcysteine, should be administered as soon as possible in accordance with National treatment guidelines.
Symptomatic treatment should be implemented.

Sodium bicarbonate
High doses of sodium bicarbonate may be expected to induce gastrointestinal symptoms including belching and nausea.
In addition, high doses of sodium bicarbonate may cause hypernatraemia; electrolytes should be monitored, and patients managed accordingly.

STORAGE CONDITION:
Store at temperature below 30°C.

SHELF LIFE:
24 months

DOSAGE FORM AND PACKING AVAILABLE:
4 effervescent tablets packed in a multi-layered (paper/LDPE/Alu/LDPE) strip & such 4 strips are packed in a carton.

NAME AND ADDRESS OF MANUFACTURER:
KUSUM HEALTHCARE PVT LTD.
Plot No. M-3, Indore Special Economic Zone,
Phase-II, Pithampur, Distt. Dhar,
Madhya Pradesh, Pin 454774, India

PRODUCT REGISTRATION HOLDER:

Pahang Pharmacy Sdn. Bhd.

Lot 5979, Jalan Teratai,
5 1/2 Mile Off Jalan Meru,
41050 Klang, Selangor, Malaysia

DATE OF REVISION OF PACKAGE INSERT
Sept 2025