

PIARON EVT (Paracetamol 500 mg Effervescent Tablets)

(Paracetamol 500mg)

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What Piaron EVT Tablets is used for

Paracetamol is an analgesic and an antipyretic.

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

How Piaron EVT Tablets works

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..

Before you use Piaron EVT Tablets

WARNING

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

- When you must not use it

Do not take this medicine if:

- you are allergic to Paracetamol or any other ingredients of this medicine (listed in Product Description)

- Before you start to use it

Pregnancy

A large amount of data on pregnant women indicate neither malformative,

nor fetoneonatal 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.

- Taking other medicine

Check with your doctor before use if you are taking warfarin or similar medicines used to thin the blood.

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Some medications and this product can interfere with each other.

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

How to use Piaron EVT Tablets

- How much to use

- •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.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Use Piaron EVT Tablets for the duration that the doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your

nearest hospital, if you think you or anyone else may have use too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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.

While you are using it

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Piaron EVT Tablets.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give Piaron EVT Tablets to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

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.

Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson Syndrome/Toxic Epidermal Necrolysis have been reported.

Side effects

Like all medicines, Piaron EVT Tablets can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

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 ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ 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.

	Epidermal Necrolysis. Very rare cases of serious skin reactions have been reported.	
Respiratory, thoracic and mediastinal disorders	Bronchospasm in patients	Very rare
Hepatobiliary disorders	Hepatic dysfunction	Very rare

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)].

Storage and Disposal of Piaron EVT Tablets

- Storage

Store at temperatures not exceeding 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Effervescent Tablets
White to off white, round shape beveled edge tablet, plain on both sides.
Slightly opalescent solution appears after dissolving the tablet in water

- Ingredients

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 and Stevens Johnson syndrome and Toxic	Very rare

- Active ingredient(s)
Each effervescent tablet Contains:
Paracetamol BP 500 mg

- Inactive ingredient
Citric acid (anhydrous Powder Grade), Sorbitol Powder, Dimethicone, Aspartame, Povidone, Sodium Bicarbonate, Anhydrous Sodium Carbonate, Sodium Lauryl Sulphate, Purified water

- MAL Number
MAL*****

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 Miles Off Jalan Meru,
41050 Klang, Selangor, Malaysia

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