TRAMP

Paracetamol 325 mg & Tramadol Hydrochloride 37.5 mg Tablet

Presentation

TRAMP Tablet: Each film coated tablet contains Paracetamol BP 325 mg & Tramadol Hydrochloride BP 37.5 mg.

Pharmacodynamic properties

The combination of Paracetamol & Tramadol combines three complementary modes of analgesic action.

- Paracetamol non-opioid, non-salicylate analgesic
- Tramadol activates opioid (μ_1) receptor
- Tramadol inhibits re-uptake of noradrenaline and serotonin

Pharmacokinetic properties

Features	Paracetamol	Tramadol Hydrochloride
Onset of action	15-30 minutes	20-30 minutes
Peak serum concentration	0.5-1 hour	approx. 2 hours
Elimination half life	2-3 hours	6 hours
Bioavailability	85-98 %	90-100%
Protein binding	10-25%	approx. 20%
Rate of metabolism in the liver	> 90 %	approx. 70%

Indications

Tramp is indicated for the management of moderate to severe pain i.e. acute dental pain, accidental pain, migraine pain, cancer pain, post surgical pain, acute & chronic low back pain, osteoarthritis and other types of pain.

Dosage and administration

For the management of moderate to severe pain, the recommended dose of Tramp is 1 or 2 tablets every 4 to 6 hours as needed for pain relief up to a maximum of 8 tablets per day. Tramp is not recommended in patients less than 12 years of age. Tramp can be administered with or without food.

Contraindications

Tramadol should not be administered to patients who have previously demonstrated hypersensitivity to Paracetamol, Tramadol and any other component of this product or opioids. It is contraindicated in any situation where opioids are contraindicated.

Side effects

The most commonly reported undesirable side effects are constipation, diarrhea, dizziness, drowsiness, increased sweating, loss of appetite and nausea.

Precautions

Tramadol should be used with caution in opioid dependent patients, or in patients with cranial trauma, in patients prone to convulsive disorder, biliary tract disorders, in a state of shock, in an altered state of consciousness for unknown reasons, with problems affecting the respiratory center or the respiratory function, or with an increased intracranial pressure. Paracetamol in overdosage may cause hepatic toxicity in some patients.

Drug interactions

Concomitant administration of Tramadol and carbamazepine may cause significantly decreased Tramadol and its metabolite M1 concentrations. Patients receiving Carbamazepine may have significantly reduced analgesic effect from Tramadol.

Concomitant administration with inhibitors of CYP2D6 such as Fluoxetine, Paroxetine, Quinidine and Amitriptyline could result in some inhibition of the metabolism of Tramadol.

Use in pregnancy and lactation

Pregnancy Category: C

There are no adequate and well-controlled studies in pregnant women. This combination preparation should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. This combination preparation is not recommended for obstetrical preoperative medication or post delivery analgesia in nursing mother because its safety in new born and infants has not been studied.

Overdose

Symptoms of Paracetamol overdose in the first 24 hours are pallor, nausea, vomiting anorexia and abdominal pain.

Symptoms of Tramadol overdosage are miosis, vomiting and convulsions.

Storage conditions

Store in cool and dry place, away from light. Keep out of the reach of children.

Commercial pack

Tramp Tablet: Each box contains 5 blister packs of 10 tablets.

Manufactured by :

general GENERAL PharmaceutIcals Ltd.
Gazipur, Bangladesh