

Atopen-X[®] Tablet

Paracetamol BP 325 mg & Tramadol Hydrochloride BP 37.5 mg

Composition

Each film coated tablet contains Paracetamol BP 325 mg and Tramadol Hydrochloride BP 37.5 mg.

Pharmacology

Tramadol is a centrally acting synthetic opioid. It is a pure non-selective agonist of the μ , κ and δ opioid receptors with higher affinity for the μ receptors. Unlike morphine, a broad range of analgesic doses of Tramadol has no respiratory depression effect.

Tramadol has been shown to inhibit re-uptake of norepinephrine & serotonin in vitro, as have some other opioids analgesics. These mechanisms may contribute independent to the overall analgesic profile of tramadol. Paracetamol is non-opiate and non-salicylate analgesic with marked anti-pyretic property. The precise mechanism of the analgesic properties of paracetamol is unknown and may involve central and peripheral mechanisms.

Indication

Atopen-X tablet is indicated for the symptomatic relief of moderate to moderately severe pain in adults. Atopen-X tablet is also indicated for the short-term (five days or less) management of acute pain.

Dosage & Administration

Atopen-X tablet can be administered without regards to meal.

- For the treatment of moderate to moderately severe pain: The recommended dose is 1 to 2 tablets every 4 to 6 hours as needed for pain relief up to a maximum of 8 tablets per day.
- In case of short-term (five days or less) treatment of acute pain: The recommended dose is 2 tablets every 4 to 6 hours as needed for pain relief up to a maximum of 8 tablets per day.
- The dosing interval should not be less than 6 hours.
- Atopen-X is not recommended in patients under 18 years of age.

Contraindication

Paracetamol & Tramadol combination tablet should not be administered to patients who are hypersensitive to Paracetamol & Tramadol or opioids. This is contraindicated in any situation where opioids are contraindicated.

Patients showing acute intoxication with alcohol or taking hypnotic drugs, centrally-acting analgesics or psychotropic drugs or with severe hepatic impairment, epilepsy not controlled by treatment and patients who are receiving monoamine oxidase (MAO) inhibitors or within two weeks of their withdrawal are also contraindicated to this drug.

Adverse Reactions

Atopen-X is well tolerated to patients. But in rare case the following adverse reactions may happen to this drug: asthenia, fatigue, hot flushes, headache, tremor, abdominal pain, constipation, diarrhoea, dyspepsia, dry mouth, nausea, dizziness, vomiting, anorexia, anxiety, confusion, euphoria, insomnia, nervousness, rash, increased sweating, somnolence and pruritus.

Precaution

- Atopen-X may impair mental or physical abilities. Do not drive a car or operate machineries while taking this drug.
- Atopen-X should not be taken with alcohol containing beverages.
- The patient should not take Atopen-X with other tramadol or paracetamol-containing products.
- Atopen-X should be used with caution when taking medications such as tranquilizers, hypnotics or other opiate containing analgesics.

Pediatric & Geriatric use

The safety and effectiveness of this combination has not been established for pediatric use.

The elderly patients with decreased hepatic, renal or cardiac function, or on multidrug therapy should take Atopen-X cautiously.

Use in Renal Disease

The use of this combination has not been studied in patients with impaired renal function.

In patients with creatinine clearances of less than 30 ml/min, it is recommended that the dosing interval of this drug must be increased but not to exceed 2 tablets every 12 hours.

Use in Hepatic Disease

The use of this combination has not been studied in patients with impaired hepatic function. So, patients with hepatic impairment should not take this drug.

Use in Pregnancy & Lactation

Pregnancy Category 'C'.

There are no adequate and well-controlled studies of using this combination in pregnant women. So, this drug should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.

Atopen-X is not recommended for obstetrical preoperative medication or for post-delivery analgesia in nursing mothers because its safety in infants and newborns has not been studied.

Storage

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

How Supplied

Atopen-X Tablet: Each box containing 2x10's tablets in blister pack.

Manufactured by :



KEMIKO PHARMACEUTICALS LTD.
Bangladesh