FASTDOL

(Paracetamol BP and Tramadol Hydrochloride BP)
Tablet

DESCRIPTION

Tramadol Hydrochloride is an opioid analgesic that acts on the central nervous system. It is a pure non selective agonists of the mu, delta, and kappa opioid receptors with a higher affinity for the mu receptors. Unlike morphine, a broad range of analgesic doses of Tramadol Hydrochloride has no respiratory depressant effect. The precise mechanism of the analgesic properties of paracetamol is unknown and may involve central and peripheral effects.

COMPOSITION

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

INDICATIONS

For the management of moderate to severe pain.

DOSAGE AND ADMINISTRATION

Adult

The recommended dose is 1 or 2 tablets every 4 to 6 hours for 5 days or less.. Additional doses can be taken as needed, not exceeding 8 tablets (equivalent to 300 mg tramadol and 2600 mg paracetamol) per day. The dosing interval should not be less than six hours.

Children

The effective and safe use of FASTDOL has not been established in children below the age of 16 years. Treatment is therefore not recommended in this population.

OR AS DIRECTED BY THE PHYSICIAN.

SIDE EFFECTS

The most commonly reported undesirable effects during the clinical trials performed with the Paracetamol/Tramadol Hydrochloride combination were nausea, dizziness and somnolence.

CONTRAINDICATIONS

Hypersensitivity to Tramadol Hydrochloride, paracetamol or to any of the ingredient of the medicinal product. FASTDOL should not be administered to patients who are receiving monoamine oxidase inhibitors or within two weeks of their withdrawal.

PRECAUTIONS

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 over dosage may cause hepatic toxicity in some patients.

PREGNANCY AND LACTATION

Pregnancy category C. Since it is a fixed combination of active ingredients including Tramadol Hydrochloride, it should not be used during pregnancy & lactation.

DRUG INTERACTIONS

Concomitant administration of CYP2D6 and/or CYP3A4 inhibitors such as quinidine, fluoxetine, paroxetine. and amitriptyline (CYP2D6 inhibitors), and ketoconazole and erythromycin (CYP3A4 inhibitors), may reduce metabolic clearance of tramadol, increasing the risk for serious adverse events including seizures and serotonin syndrome.

SUPPLY

Each Box contains 3x10 tablets in blister strips.

Keep all medicines out of reach of the children.
Store in a cool and dry place, protected from light.

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Further information is available on request

FOR HEALTH, VIGOUR AND HAPPINESS

The ACME Laboratories Ltd.

DHAKA, BANGLADESH.