

NapaDol[®]

Paracetamol 325mg & Tramadol Hydrochloride 37.5mg Tablet

Description

Tramadol Hydrochloride is an opioid analgesic that acts on the central nervous system. Tramadol Hydrochloride is a pure non selective agonists of the m, d, and k opioid receptors with a higher affinity for the m 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.

Indications

For the symptomatic treatment of moderate to severe pain.

Dosage and Administration

For the management of pain, the recommended dose is 1 or 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 six hours. NapaDol is not recommended in patients under 18 years of age.

Pregnancy and Lactation

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

Contraindications

Hypersensitivity to Tramadol Hydrochloride, paracetamol or to any of the excipients of the medicinal product. Acute intoxication with alcohol, hypnotic drugs, centrally-acting analgesics, opioids or psychotropic drugs. Should not be administered to patients who are receiving monoamine oxidase inhibitors or within two weeks of their withdrawal. Severe hepatic impairment. Epilepsy not controlled by treatment.

Adverse Reactions

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

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 overdose may cause hepatic toxicity in some patients. At therapeutic doses, Tramadol Hydrochloride has the potential to cause withdrawal symptoms. Rarely, cases of dependence and abuse have been reported.

Pharmaceutical Precaution

Store in cool & dry place, away from children.

Commercial Pack

NapaDol® Tablet: Box containing 30 tablets in 3x10's blister strips. Each film coated tablet contains Paracetamol BP 325 mg & Tramadol Hydrochloride BP 37.5 mg.

Manufactured by

Beximco Pharmaceuticals Ltd.

TONGI, BANGLADESH

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