

Kingdol

(Tramadol Hydrochloride BP 100mg)

Composition: Each suppository contains Tramadol Hydrochloride BP 100mg.

Pharmacology: Tramadol is a centrally acting synthetic analgesic compound. It inhibits the re uptake of neurotransmitters- serotonin and noradrenaline. Thus it modifies the transmission of pain impulses by activating both descending serotonergic pathways and noradrenergic pathways involved in analgesia. The analgesic effects of Tramadol are mediated via stimulation of mu-opioid receptors and indirect modulation of central monoaminergic inhibitory pathways.

Indication: Tramadol is used for the treatment of moderate to severe painful conditions. These include: Postoperative pain, Colic and spastic pain, Cancer pain, Joint pain, Neck and back pain, Pain associated with osteoporosis.

Dosage & Administration: Tramadol suppository should be administered rectally. For adults usual dose is 100 mg Tramadol Hydrochloride 6 hourly. In general, 400 mg Tramadol Hydrochloride (4 Tramadol suppository) per day sufficient. However, for the treatment of Cancer pain and severe pain after operations much higher daily doses can be used. Or, as directed by the registered physician.

Contraindications: Tramadol is contraindicated in patients having hypersensitivity to this drug. It is also contraindicated in acute intoxication with alcohol, hypnotics, centrally acting analgesics, opioids or psychotropic drugs.

Precautions: Respiratory depression: When large doses of tramadol are administered with anesthetic medications or alcohol, respiratory depression may result. Therefore, tramadol should be administered cautiously in patients at risk for respiratory depression. **Opioid dependence:** Tramadol is not recommended for patients who are dependent on opioids. **Concomitant CNS depressants:** Tramadol should be used with caution and in reduced dosages when administering to patients or sedative receiving CNS depressant such as alcohol, opioids, anesthetic agents, phenothiazines, tranquilizers hypnotics. **Concomitant MAO inhibitors:** Tramadol should be used with great caution in patients taking MAO inhibitors, since tramadol inhibits the uptake of norepinephrine and serotonin. Tramadol should be used with caution in patients with increased intracranial pressure or head injury and patients with acute abdominal conditions.

Side effects: Commonly occurring side-effects are dizziness/vertigo, nausea, constipation, headache, somnolence, vomiting, pruritus, CNS stimulation, asthenia, sweating, dyspepsia, dry mouth, diarrhoea. Less commonly occurring side-effects include malaise, allergic reaction, weight loss, vasodilation, palpitations, abdominal pain, anorexia, flatulence, GI bleeding, hepatitis, stomatitis etc.

Use in Pregnancy and Lactation: Safe use of Tramadol in pregnancy has not been established. Tramadol has been shown to cross the placenta. There are no adequate and well-controlled studies in pregnant women. Therefore, Tramadol should be used during pregnancy only if the potential benefit justifies the risk to the foetus. Tramadol Hydrochloride should not be administered during breastfeeding as Tramadol and its metabolites have been detected in breast milk.

Use in Child: In children from the age of 1 year Tramadol Hydrochloride can be given in a dose of 1-2 mg/kg body weight. However, suppository (100 mg Tramadol Hydrochloride) should not be administered in children and adolescents below the age of 14 years. Tramadol Hydrochloride 100 mg SR Capsules has not been studied in children. Therefore, safety and efficacy have not been established and the product should not be used in children.

Overdose: Symptoms of over dosage with tramadol are similar to those of other centrally acting, analgesics (opioids) and include miosis, vomiting, cardiovascular collapse, consciousness, disorders including coma, convulsions, respiratory depression and respiratory arrest.

Storage: Store below 25° C. Protect from light and moisture. Keep the medicine out of reach of children.

Packaging: Each box contains 10's suppositories in blister pack.



Manufactured by
DRUG INTERNATIONAL LTD.
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