

Lucidol®

Tramadol Hydrochloride Capsule

Description

Lucidol (Tramadol Hydrochloride) is a centrally acting analgesic. Tramadol is a synthetic analog of codeine. However, Tramadol has a lower affinity for opioid receptor than codeine. It is less potential for abuse or respiratory depression than other opiate agonist, but both may occur.

Indications

Lucidol is indicated for the management of moderate to severe pain.

Dosages and Administration

For the treatment of painful conditions, Lucidol 50 mg to 100 mg can be administered as needed for relief every four to six hours, not to exceed 400 mg per day. For moderate pain, Lucidol 50 mg may be adequate as the initial dose, and for more severe pain, Lucidol 100 mg is usually more effective as the initial dose.

Contraindications

Lucidol should not be administered to patients who have previously demonstrated hypersensitivity to tramadol, any other component of this product, or opioids. It is also contraindicated in cases of acute intoxication with alcohol, hypnotic, centrally acting analgesics, opioids or psychotropic drugs.

Precautions

Lucidol should be administered cautiously in patients at risk for respiratory depression. When large doses of Lucidol are administered with anaesthetic medications or alcohol, respiratory depression may result. Lucidol should be used with caution in patients with increased intracranial pressure or head injury. Pupillary changes (miosis) from Tramadol may obscure the existence, extent, or course of intracranial pathology.

Lucidol is not recommended for patients who are dependent on opioids. Patients who have recently taken substantial amounts of opioids may experience withdrawal symptoms.

Impaired renal function results in a decreased rate and extent of excretion of Tramadol and its active metabolite. In patients with creatinine clearances of less than 30 ml/min, reduction of doses is recommended.

Side Effects

Most common side effects (Incidence 1% to less than 5% in clinical trials) are malaise, vasodilatation, anxiety, confusion, coordination disturbance, euphoria, nervousness, sleep disorder, abdominal pain, anorexia, flatulence, hypertonia, skin rash, visual disturbance, urinary retention, urinary frequency, and menopausal symptoms.

Other infrequently reported side effects are abnormal ECG, hypertension, myocardial ischaemia, palpitations, migraine, gastrointestinal bleeding etc.

Use in Special Populations

Pregnancy : Tramadol should not be used in pregnant women prior to or during labor unless the potential benefits outweigh the risks. Safe use in pregnancy has not been established. Chronic use during pregnancy may lead to physical dependence and post-partum withdrawal symptoms in the newborn.

Lactation : Tramadol 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.

Paediatric use : The paediatric use of Tramadol is not recommended because safety and efficacy in patients under 16 years of age have not been established.

Commercial Pack

Lucidol® Capsule : Box containing 3 x 10's capsules in blister strips. Each capsule contains Tramadol Hydrochloride BP 50 mg.