PRESCRIBING INFORMATION

LAMADOL® Injection IM/IV
(Tramadol HCl)

لیماڈول انجکشن آئی ایم/آئی وی

COMPOSITION:
Each 2ml contains:
Tramadol HCl.....USP...100mg
Mfg. Specs. Brookes

DESCRIPTION:
Lamadol (Tramadol HCl) Injection is a centrally acting synthetic opioid analgesic. The mode of action is not completely understood at least two complementary mechanisms appear applicable e.g. binding of parent and M1 metabolite to μ-opioid receptors and weak inhibition of reuptake of nor-epinephrine and serotonin. Opioid activity is due to both low affinity binding of the parent compound and higher affinity binding of the O-demethylated metabolite M1 to μ-opioid receptors.

Lamadol (Tramadol HCl) Injection induced analgesia is only partially antagonized by the opiate antagonist naloxone. Lamadol (Tramadol HCl) Injection has been shown to inhibit reuptake of nor-epinephrine and serotonin in vitro. These mechanisms may contribute independently to the overall analgesic profile of tramadol. Apart from analgesia Lamadol (Tramadol HCl) Injection administration may produce a constellation of symptoms (including dizziness, somnolence, nausea, constipation, sweating and pruritus) similar to that of other opioids.

Lamadol (Tramadol HCl) Injection has not been shown to cause histamine release. At therapeutic doses, Lamadol (Tramadol HCl) Injection has no effect on heart rate, left-ventricular function or cardiac index. Orthostatic hypotension has been observed.

INDICATIONS:
Lamadol (Tramadol HCl) Injection is indicated for the management of moderate to moderately severe chronic pain in adults who require round-the-clock treatment of their pain for an extended period of time.

DOSAGE AND ADMINISTRATION:
The dosage should be adjusted to the intensity of the pain and the sensitivity of the individual patient. The dosage of Lamadol (Tramadol HCl) Injection in adults and adolescents above the age of 14 years is One Injection (2ml) IM or IV in the morning and evening.

However, in the treatment of tumor pain and severe postoperative pain much higher doses can be given. On the basis of this recommended dosage the doctor may adjust the interval between doses to individual requirements, whereby it should not be less than six hours. Start Lamadol (Tramadol HCl) Injection at the lowest possible dose and titrate upward as tolerated to achieve an adequate effect. Clinical studies have not demonstrated a clinical benefit at a total daily dose exceeding 300mg.

SYMPTOMS AND EMERGENCY MEASURES IN OVERDOSAGE
(INSTRUCTIONS FOR THE DOCTORS)
The following typical symptoms have been observed reduced level of consciousness up to coma generalized epileptic seizures, hypotension, tachycardia, constricted or dilated pupils, respiratory depression up to respiratory arrest. These effect may be abolished by the administration of an opiate antagonist (e.g. naloxone) to be given carefully in repeated small doses, as the duration of effect is shorter than that of Lamadol (Tramadol HCl) Injection In addition intensive care measures (in particular intubations and ventilation) should be initiated. In the event of convulsions the administration of benzodiazepines should be considered. Moreover, measures to prevent heat loss and fluid replacement may be necessary.

CONTRAINDICATIONS
Lamadol (Tramadol HCl) Injection should not be administered to patients who have hypersensitivity to tramadol, or any other component of this product or opioids.

SIDE-EFFECTS:
Lamadol (Tramadol HCl) Injection is relatively safe opioid analgesic having few side effects e.g. Nausea, sweating, dry mouth, dizziness may occasionally occur in rare cases there may be effects on cardiovascular regulation (palpitation, tachycardia, tendency towards collapse up to cardiovascular collapse). These side-effects may occur particularly in an upright position, on intravenous administration and in patients under physical strain.

In rare cases headache, retching, vomiting, constipation, gastrointestinal irritation, pruritus, exanthema may also occur. In very rare cases Lamadol (Tramadol HCl) Injection may cause various psychic side-effects which vary individually in intensity and nature (depending on personality and duration of medication). These include changes in mood (usually elation, occasionally dysphoria), changes in activity (usually suppression occasionally increase) and changes in cognitive and sensorial capacity (e.g. decision behavior, perception disorders).

Lamadol (Tramadol HCl) Injection causes various dose-dependent degrees of respiratory depression and sedation on long-term use tolerance, psychic and physical dependence may develop.

Note: Even when taken, according, to instructions Lamadol (Tramadol HCl) Injection may affect reaction to such an extent that the patient's capacity to drive or operate machines may be impaired. This applies particularly in conjunction with alcohol.

USE IN SPECIAL POPULATIONS:

Renal Disease Patients

Impaired renal function results in a decreased rate and extent of excretion of tramadol and its active metabolite, M1. The pharmacokinetics of Lamadol (Tramadol HCl) Injection were studied in patients with mild or moderate renal impairment after receiving multiple doses of Lamadol (Tramadol HCl) Injection. There is no consistent trend observed for Lamadol (Tramadol HCl) Injection exposure related to renal function in patients with mild (CLcr: 50-80 mL/min) or moderate (CLcr: 30-50 mL/min) renal impairment in comparison to patients with normal renal function. However, Lamadol (Tramadol HCl) Injection does not permit the dosing flexibility required for safe use in patients with severe renal impairment.

Hepatic Impairment

Lamadol (Tramadol HCl) Injection should not be used in patients with severe hepatic impairment.

Geriatric

The effect of age on the absorption of Lamadol (Tramadol HCl) Injection in patients over the age of 65 years has not been studied and is unknown.

Pregnancy:

Pregnancy category–C, Lamadol (Tramadol HCl) Injection should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers:

Lamadol (Tramadol HCl) Injection 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.

DRUG INTERACTION :

The concomitant administration of Lamadol (Tramadol HCl) Injection and other centrally depressant drugs or alcohol may intensify the central nervous side-effects of Lamadol (Tramadol HCl) Injection in particular respiratory depression. Lamadol (Tramadol HCl) Injection should not be used in patients receiving MAO inhibitors and neuroleptic drugs.

STORAGE:

Store at temperature 15 to 30 °C away from light.

PRESENTATION:

Lamadol (Tramadol HCl) Injection is available in a box of 5x2ml Ampoules.

مقدار اور طریقہ استعمال:

لیماڈول انجکشن کو درد کی شدت اور مریض کی برداشت کے مطابق لگانا چاہیئے۔ 14 سال سے بڑی عمر میں ایک انجکشن پٹھوں میں یا وریدی راستے سے صبح اور شام دینا چاہیے۔

کینسر کے درد اور آپریشن کے بعد شدید درد کی صورت میں زیادہ سے زیادہ بھی لگائے جاسکتے ہیں۔ایک سے دوسرے انجکشن کے درمیان کم سے کم 6 گھنٹے کا وقفہ رکھیں۔

عام طور سے کم مقدار سے انجکشن شروع کیا جاتا ہے اور پھر اس کی مقدار کو تکلیف کی شدت کو دیکھتے ہوئے بڑھایا جاسکتا ہے۔ ریسرچ سے معلوم ہوا ہے کہ روزانہ کی کل مقدار 300 ملی گرام سے نہ بڑھے۔

اسٹوریج:

15 سے 30 ڈگری سینٹی گریڈ درجہ حرارت پر روشنی سے بچا کر رکھیئے۔

brookes

Manufactured by:

Brookes Pharma Private Limited
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Karachi 74900 Pakistan.

ISO 9001
ISO14001
OHSAS 18001
BUREAU VERITAS
Certification