Only for the use of Medical Professionals

Lopenta®

Tapentadol

Description

Lopenta® (Tapentadol Hydrochloride) is a centrally acting synthetic opioid. The analgesic activity of **Lopenta®** is due to its μ-receptor agonistic activity and inhibition properties of norepinephrine reuptake.

Indications

Lopenta® is indicated for the relief of moderate to severe acute pain in patients 18 years of age or older.

Dosage and administration

The dosing regimen should be individualized according to the severity of pain being treated, the previous experience with similar drugs and the ability to monitor the patient. **Lopenta®** may be given with or without food.

Usual dosage: The dose is 50 mg, 75 mg or 100 mg every 4 to 6 hours depending upon pain intensity. On the first day of dosing, the second dose may be administered as soon as one hour after the first dose, if adequate pain relief is not attained with the first dose. Subsequent dosing is 50 mg, 75 mg or 100 mg every 4 to 6 hours and should be adjusted to maintain adequate analgesia with acceptable tolerability.

Maximum dosage: Daily doses greater than 700 mg on the first day of therapy and 600 mg on subsequent days have not been studied and are not recommended.

Use in pregnancy & lactation

Pregnancy category C. There are no adequate and well controlled studies of Tapentadol in pregnant women. Tapentadol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Tapentadol should not be used in women during and immediately prior to labor. Due to insufficient information on the excretion of Tapentadol in human breast milk, it should not be used during breast feeding.

Use in children

The safety and effectiveness of Tapentadol in pediatric patients less than 18 years of age have not been established and is not recommended in this population.

Use in elderly

Recommended dose for elderly patients with normal renal and hepatic function is the same as for younger adult patients with normal renal and hepatic function. Consideration should be given to starting elderly patients with the lower range of recommended doses.

Use in hepatic impairment

Mild impairment: No dosage adjustment is required.

Moderate impairment: Initial dose should be 50 mg with the interval between doses not less than every 8 hours (maximum of three doses in 24 hours). Maintenance of analgesia with acceptable tolerability could be achieved by either shortening or lengthening the dosing interval.

Severe impairment: Not recommended.

Use in renal impairment

Mild to moderate impairment: No dosage adjustment is required.

Severe impairment: The safety and effectiveness has not been established.

Adverse reactions
Increased or decreased heart rate, visual disturbance, paresthesia, disturbance in attention, sedation, memory impairment, ataxia, presyncope, syncope, respiratory depression, urticaria.

Contra-indications
Tapentadol is contraindicated in patients with significant respiratory depression, acute or severe bronchial asthma or hypercapnia in an unmonitored setting or in the absence of resuscitative equipment. Tapentadol is also contraindicated in patients with known or suspected paralytic ileus.

Precautions
Tapentadol should be administered with caution to patients with conditions accompanied by hypoxia, hypercapnia, asthma, COPD, severe obesity, sleep apnea syndrome, myxedema, kyphoscoliosis, CNS depression and history of seizure. Tapentadol should be avoided in patients with head injury, increased intracranial pressure and coma. Use with caution in patients currently using or within 14 days of using a MAOI (monoamine oxidase inhibitor).

Drug interactions
Using CNS depressants may lead to increased risk of respiratory depression, hypotension, profound sedation, coma or death. When combined therapy with CNS depressant is contemplated, the dose of one or both agents should be reduced. Monitor for signs of serotonin syndrome when Tapentadol is used concomitantly with SSRIs, SNRIs, tricyclic antidepressants or triptans.

Overdose
Management of overdose should be focused on treating symptoms (miosis, vomiting, cardiovascular collapse, consciousness disorders up to coma, convulsions and respiratory depression up to respiratory arrest) of μ-opioid agonism. Primary attention should be given to re-establishment of a patent airway and institution of assisted or controlled ventilation when overdose of Tapentadol is suspected. Supportive measures (including oxygen and vasopressors) should be employed in the management of circulatory shock and pulmonary edema accompanying overdose as indicated. Cardiac arrest or arrhythmias may require cardiac massage or defibrillation. Pure opioid antagonist, such as naloxone, are specific antidotes to respiratory depression resulting from opioid overdose. Gastrointestinal decontamination with activated charcoal or by gastric lavage is only recommended within 2 hours after intake. Gastrointestinal decontamination at a later time point may be useful in case of intoxication with exceptionally large quantities.

Pharmaceutical precautions
Keep away from the reach of children. Store in a cool and dry place protected from light.

Presentation
Lopenta® 50 tablet: Each coated tablet contains Tapentadol 50 mg as Hydrochloride INN.
Lopenta® 75 tablet: Each coated tablet contains Tapentadol 75 mg as Hydrochloride INN.

Package quantities
Lopenta® 50 tablet: Carton of 20 tablets in blister pack.
Lopenta® 75 tablet: Carton of 10 tablets in blister pack.

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