TAPENTA®

Tapentadol Hydrochloride film coated tablet

DESCRIPTION

TAPENTA® is a preparation of Tapentadol Hydrochloride. Tapentadol is a centrally-acting synthetic opioid analgesic. Although its exact mechanism is unknown, analgesic efficacy is thought to be due to ų-opioid agonist activity and the inhibition of norepinephrine reuptake.

INDICATIONS

Indicated for the relief of moderate to severe acute pain in patients 18 years of age or older.

DOSAGE AND ADMINISTRATION

Initiate **TAPENTA®** with or without food at a dose of 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. Daily doses greater than 700 mg on the first day of therapy and 600 mg on subsequent days have not been studied and are, therefore, not recommended.

CONTRAINDICATIONS

- Impaired pulmonary function (significant respiratory depression, acute or severe bronchial asthma or hypercapnia in unmonitored settings or the absence of resuscitative equipment.
- Paralytic ileus.
- Concomitant use with monoamine oxidase inhibitors (MAOI) or use within 14 days.

SIDE-EFFECTS

The most common adverse events were nausea, dizziness, vomiting and somnolence.

PRECAUTIONS AND WARNING

- Respiratory depression: Increased risk in elderly, debilitated patients, those suffering from conditions accompanied by hypoxia, hypercapnia, or upper airway obstruction.
- CNS effects: Additive CNS depressive effects when used in conjunction with alcohol, other opioids, or illicit drugs.
- Elevation of intracranial pressure: May be markedly exaggerated in the presence of head injury, other intracranial lesions.
- Abuse potential may occur. Monitor patients closely for signs of abuse and addiction.
- Impaired mental/physical abilities: Caution must be used with potentially hazardous activities.
- Seizures: Use with caution in patients with a history of seizures.
- Serotonin Syndrome: Potentially life-threatening condition could result from concomitant serotonergic administration.

USE IN PREGNANCY AND 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. There is insufficient/limited information on the excretion of tapentadol in human or animal breast milk. Physicochemical and available pharmacodynamic/toxicological data on tapentadol point to excretion in breast milk and risk to the suckling child cannot be excluded. Tapentadol should not be used during breast-feeding.

PHARMACEUTICAL PRECAUTION

Keep away from light and moisture. Keep out of reach of children.

PACKAGING

TAPENTA® 50 tablet : Box containing 2 strips of 10 tablets each. Each film coated tablet contains Tapentadol Hydrochloride INN equivalent to Tapentadol 50 mg.

TAPENTA® 75 tablet : Box containing 1 strip of 10 tablets. Each film coated tablet contains Tapentadol Hydrochloride INN equivalent to Tapentadol 75 mg.

TAPENTA® 100 tablet : Box containing 1 strip of 10 tablets. Each film coated tablet contains Tapentadol Hydrochloride INN equivalent to Tapentadol 100 mg.

SK+F

Manufactured by:
ESKAYEF PHARMACEUTICALS LTD.
MIRPUR, DHAKA, BANGLADESH

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