Abridged Prescribing Information

Active Ingredient: HITAP-ER 50/100 tablets contain tapentadol extended release 50 mg /100 mg

Indication: Management of moderate to severe chronic pain in adults when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. **Dosage & Administration:** (i) Patients Currently Not Taking Opioid Analgesics: The starting dose of Tapentadol ER in patients currently not taking opioid analgesics is 50 mg twice a day (approximately every 12 hours). Individually titrate the dose within the therapeutic range of 100 mg to 250 mg twice daily. (ii) Patients Currently Taking Opioid Analgesics: The initial dose of Tapentadol ER in patients previously taking other opioids is 50 mg titrated to an effective and tolerable dose within the therapeutic range of 100 mg to 250 mg twice daily. **Contraindications:** Hypersensitivity to tapentadol or to any of the excipients. In situations where active substances with mu-opioid receptor agonist activity are contraindicated, i.e. patients with significant respiratory depression (in unmonitored settings or the absence of resuscitative equipment), and patients with acute or severe bronchial asthma or hypercapnia. In any patient who has or is suspected of having paralytic ileus. In patients with acute intoxication with alcohol, hypnotics, centrally acting analgesics, or psychotropic active substances. **Warnings & Precautions:** Respiratory Depression, CNS Depression, Head Injury and Increased Intracranial Pressure, Hypotension, Misuse and Abuse, Seizures, Serotonin Syndrome Risk, Use in Pancreatic/Biliary Tract Disease Tapentadol ER should be used with caution in the following conditions: adrenocortical insufficiency (e.g., Addison's disease); delirium tremens; myxedema or hypothyroidism; prostatic hypertrophy or urethral stricture; and, toxic psychosis. **Pregnancy & Lactation:** Pregnancy Category C. Tapentadol ER should not be used during breast-feeding. **Drug Interaction:** Patients receiving other opioid agonist analgesics, general anesthetics, phenothiazines, antiemetics, other tranquilizers, sedatives, hypnotics, centrally acting muscle relaxants, or other CNS depressants (including alcohol) concomitantly with Tapentadol ER may experience additive CNS depression. Interactive effects resulting in respiratory depression, hypotension, profound sedation, or coma may result if these drugs are taken in combination with Tapentadol ER. Tapentadol ER is contraindicated in patients who are receiving monoamine oxidase (MAO) inhibitors. Caution is advised when Tapentadol ER is co-administered with other drugs that may affect serotonergic neurotransmitter systems such as SSRIs, SNRIs, MAOIs, and triptans. e concomitant use of Tapentadol ER with mixed agonist/antagonists (e.g., butorphanol, nalbuphine, and pentazocine) and partial agonists (e.g., buprenorphine) could lead to a reduction of the analgesic effect by competitive blocking of opioid receptors, and/or withdrawal. Therefore, this combination is not recommended. The use of Tapentadol ER with anticholinergic products may increase the risk of urinary retention and/or severe constipation, which may lead to paralytic ileus. **Adverse Reactions:** Respiratory Depression, CNS Depression, Hypotension, Seizures, Serotonin Syndrome. **Overdose:** Experience with Tapentadol ER overdose is very limited. Preclinical data suggest that symptoms like those of other centrally acting analgesics with mu-opioid agonist activity are to be expected upon intoxication with tapentadol. In principle, the clinical manifestations of opioid overdose include miosis, vomiting, cardiovascular collapse, consciousness disorders up to coma, convulsions and respiratory depression up to respiratory arrest, and death. Supportive measures (including oxygen and vasopressors) should be employed in the management of cardiac and/or pulmonary failure as needed. Cardiac arrest or arrhythmias may require cardiac massage or defibrillation. Take the extended-release characteristics of Tapentadol ER into account when treating the overdose. Even in the face of improvement, continued medical monitoring is required because of the possibility of extended effects. Pure opioid antagonists, such as naloxone, are specific antidotes to respiratory depression resulting from opioid overdose. *(For further details, please refer full prescribing information)*

Version date: 24 /02/20. If you require any further information, please reply us on productqueries@intaspharma.com