TAPRISE NS

To be sold by retail on the prescription of Medical Specialist for use in Hospital / Institutional setup only

Abbreviated Prescribing information for TAPRISE NS [Tapentadol Hydrochloride Nasal Spray 225 mg/ml]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Tapentadol HCl is a centrally acting synthetic analgesic. Although its exact mechanism is unknown, analgesic efficacy is thought to be due to mu-opioid agonist activity and the inhibition of norepinephrine reuptake.

INDICATIONS: TAPRISE NS is indicated for treatment of moderated to severe post- operative pain in hospital admitted patients.

DOSAGE AND ADMINISTRATION: The recommended dose is 45 mg (one spray in each nostril) every 4-6 hr for a period not exceeding 5 days. Additional one dose of TAPRISE NS may be administered after 1 hr of first dose if adequate pain relief is not attained with the first dose.

CONTRAINDICATION: TAPRISE NS is contraindicated in: •Patients with hypersensitivity to active substances or to any of the excipients of this product • 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 • any patient who has or is suspected of having paralytic ileus • patients who are receiving monoamine oxidase (MAO) inhibitors or who have taken them within the last 14 days due to potential additive effects on norepinephrine levels which may result in adverse cardiovascular events.

WARNINGS & PRECAUTIONS: TAPRISE NS has a potential for abuse and addiction in a manner similar to other opioid agonists. This should be considered when prescribing or dispensing TAPRISE NS in situations where there is concern about an increased risk of misuse, abuse, addiction, or diversion. concomitant prescribing with these sedating medicinal products should be reserved for patients for whom alternative treatment options are not possible. TAPRISE NS should be administered with caution to patients with impaired respiratory functions. TAPRISE NS should not be used in patients who may be particularly susceptible to the intracranial effects of carbon dioxide retention such as those with evidence of increased intracranial pressure, impaired consciousness, or coma. TAPRISE NS should be prescribed with care in patients with a history of a seizure disorder. TAPRISE NS should be used with caution in patients with moderate hepatic impairment, especially upon initiation of treatment. In patients maintained on buprenorphine for the treatment of opioid dependence, alternative treatment options (like e.g. temporary buprenorphine discontinuation) should be considered. For patients on tapentadol HCl treatment, caution should be exercised if concomitant drug administration of strong enzyme inducing drugs (e.g. rifampicin, phenobarbital, St John's Wort (hypericum perforatum)) starts or stops, since this may lead to decreased efficacy or risk for adverse effects, respectively.

DRUG INTERACTIONS: Depression Patients receiving other mu-opioid agonist analgesics, general anesthetics, phenothiazines, other tranquilizers, sedatives, hypnotics, or other CNS depressants (including alcohol) concomitantly with TAPRISE NS may exhibit additive CNS depression. Care should be taken when combining TAPRISE NS with mixed mu-opioid agonist/antagonists (like pentazocine, nalbuphine) or partial mu-opioid agonists (like buprenorphine). The development of a potentially life-threatening serotonin syndrome may occur, particularly with concomitant use of serotonergic drugs such as Selective Serotonin Reuptake Inhibitors (SSRIs), SNRIs, tricyclic antidepressants (TCAs), MAOIs and triptans, and with drugs that impair metabolism of serotonin (including MAOIs). This may occur within the

recommended dose.

ADVERSE REACTIONS: Vomiting, nausea, constipation, gastroesophageal reflux disease, headache, somnolence, hypoaesthesia, hypertension, sleep disorder, nasal discomfort, nasal crusting, epistaxis, nasal pruritus, pruritus generalized, postoperative wound infection, dysuria, pyrexia, alt increased, AST increased, GGT increased, blood glucose increased*, glucose urine present, rhinorrhea, dizziness, burning sensation, post nasal drip, oropharyngeal pain, nasal crusting, nasal obstruction, sneezing, throat irritation, and nasopharyngitis.

MARKETED BY:

TORRENT PHARMA

Torrent Pharmaceuticals Limited.

IN/TAPRISE NS 22.5 mg/0.1 ml/MAR 2026/04/ABPI

(Additional information is available on request)