TAPRISE NS

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.

Abbreviated Prescribing information for TAPRISE NS (Tapentadol Hydrochloride Nasal Spray**)**

[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.

DOSAGE AND ADMINISTRATION: As directed by physician.

CONTRAINDICATION: 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: *Potential for Abuse and Addiction/Dependence Syndrome:* 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. *Risk from concomitant use of sedating medicinal products such as benzodiazepines or related substances*: Concomitant use of TAPRISE NS and sedating medicinal products such as benzodiazepines or related substances may result in sedation, respiratory depression, coma and death. Because of these risks, concomitant prescribing with these sedating medicinal products should be reserved for patients for whom alternative treatment options are not possible. *Respiratory Depression:* At high doses or in mu-opioid receptor agonist sensitive patients, TAPRISE NS may produce dose-related respiratory depression. Therefore, TAPRISE NS should be administered with caution to patients with impaired respiratory functions. *Head Injury and Increased Intracranial Pressure:* 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 used with caution in patients with head injury and intracranial lesions. *Seizures:* TAPRISE NS should be prescribed with care in patients with a history of a seizure disorder or any condition that would put the patient at risk of seizures. *Hepatic Impairment:* Subjects with hepatic impairment show higher serum concentrations than in those with normal hepatic function hence TAPRISE NS should be used with caution in patients with moderate hepatic impairment, especially upon initiation of treatment. *Mixed opioid agonists/antagonists*: Care should be taken when combining TAPRISE NS with mixed mu-opioid agonist/antagonists (like pentazocine, nalbuphine) or partial mu-opioid agonists (like buprenorphine). In patients maintained on buprenorphine for the treatment of opioid dependence, alternative treatment options (like e.g. temporary buprenorphine discontinuation)

should be considered, if administration *of full mu-agonists (like tapentadol HCL) becomes necessary in acute pain situations.*

DRUG INTERACTION: Sedative medicines such as benzodiazepines or related drugs Depression Patients receiving other mu-opioid agonist analgesics, general anesthetics, phenothiazines, other tranquilizers, sedatives, hypnotics, or other CNS depressants (including alcohol), Serotonin Syndrome Risk , the development of a potentially life-threatening serotonin syndrome may occur, particularly with concomitant use of serotonergic drugs such as 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. Serotonin syndrome may include mentalstatus changes (e.g., agitation, hallucinations, coma), autonomic instability (e.g., tachycardia, labile blood pressure, hyperthermia), neuromuscular aberrations (e.g., hyperreflexia, incoordination) and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). Withdrawal of the serotoninergic medicinal products usually brings about a rapid improvement. Treatment depends on the nature and severity of the symptoms, For patients on tapentadol 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.

ADVERSE REACTIONS: Vomiting, Nausea, Constipation, Gastroesophageal reflux disease, Headache, Somnolence, Hypoaesthesia, Hypertension, Sleep disorder, Nasal discomfort, Nasal crusting, Epistaxis, Nasal pruritus, Pruritus, Pruritus generalised, Tachycardia, Postoperative wound infection, Dysuria, Pyrexia

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/TAPENTADOL NS 22.5 mg/100 µl/May-2021/01/ABPI

(Additional information is available on request)