

GEMITROL NS

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only
Abbreviated Prescribing information for Gemitrol NS (Calcitonin (Salmon) Nasal Spray)
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: GEMITROL (Calcitonin-salmon) Nasal Spray is a synthetic polypeptide of 32 amino acids in the same linear sequence that is found in calcitonin of salmon origin. **INDICATIONS:** Gemitrol NS Nasal Spray is indicated for: Treatment of postmenopausal osteoporosis, Bone pain associated with osteolysis and/or osteopenia, Paget's disease of bone (osteitis deformans), Neurodystrophic disorders (synonymous with algodystrophy or Sudeck's disease) due to various etiological and predisposing factors such as posttraumatic painful osteoporosis, reflex dystrophy, shoulder-arm syndrome, causalgia, drug-induced neurotrophic disorders. **DOSAGE AND ADMINISTRATION:** *Osteoporosis:* The recommended dosage of Gemitrol NS Nasal Spray for the treatment of established post-menopausal osteoporosis is 200 IU once a day administered intranasally, alternating nostrils daily. *Bone pain associated with osteolysis and/or osteopenia:* 200-400 IU daily. Up to 200 IU may be administered as a single dose; in cases where a higher dosage is required it should be given in divided doses. *Paget's disease:* 200 IU daily as a single dose. In some cases 400 IU in divided doses may be necessary at the beginning of therapy. *Neurodystrophic disorders:* Early diagnosis is essential and treatment should start as soon as the diagnosis is confirmed. 200 IU daily in a single dose over a period of 2-4 weeks. **CONTRAINDICATIONS:** Hypersensitivity to synthetic calcitonin (salmon) or to any of the excipients of the formulation. Calcitonin is also contraindicated in patients with hypercalcemia. **DRUG INTERACTIONS:** Concomitant use of calcitonin and lithium may lead to a reduction in plasma lithium concentrations. The dose of lithium may need to be adjusted. **WARNINGS & PRECAUTIONS:** Periodical nasal examinations with visualization of the nasal mucosa, turbinates, septum and mucosal blood vessel status are recommended. Caution required for ulceration, allergic reactions, anaphylactic shock and dizziness. **ADVERSE REACTIONS:** Nasal discomfort, Dizziness, headache, dysgeusia, Visual disturbance, Rhinitis (including nasal dryness, nasal oedema, nasal congestion, sneezing, allergic rhinitis), nasal discomfort (e.g. nasal irritation, nasal odour, rash papular, parosmia, nasal mucosal erythema, mucosal excoriation). Rhinitis ulcerative, sinusitis, epistaxis, pharyngitis, Cough, Nausea, diarrhoea, abdominal pain, Vomiting, Pruritus, Flushing, Hypertension, Fatigue, Influenza-like symptoms, oedema (facial, extremities and generalized). tachycardia, hypotension, circulatory collapse and anaphylactic shock.

Marketed by:

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(Additional information is available on request)