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 solution USP)

[Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Calcitonin is a polypeptide hormone secreted by the parafollicular cells of the thyroid gland in the mammals and by the ultimobranchial gland of birds and fish. Calcitonin acts primarily on bone, but direct renal effects and actions on the gastrointestinal tract are recognized. Calcitonin (salmon) appears to have actions essentially identical to calcitonins of mammalian origin, but its potency per mg is greater and it has a longer duration of action. The actions of calcitonin on bone and its role in normal human bone physiology are still not completely elucidated, although calcitonin receptors have been discovered in osteoclasts and osteoblasts. Calcitonin is a calciotropic hormone, which inhibits bone resorption by a direct action on osteoclasts. By inhibiting osteoclast activity via its specific receptors, calcitonin (salmon) decreases bone resorption. Calcitonin markedly reduces bone turnover in conditions with an increased rate of bone resorption such as osteoporosis. The absence of mineralisation defect with calcitonin has been demonstrated by bone histomorphometric studies both in man and in animals. In pharmacological studies calcium has been shown to have analgesic activity in animal models. Intranasal calcitonin produces a clinically relevant biological response in humans after only a single dose, as shown by an increase in the urinary excretion of calcium, phosphorus and sodium (by reducing their tubular re-uptake) and a decrease in the urinary excretion of hydroxyproline. Long term administration of intranasal calcitonin significantly suppresses biochemical markers of bone turnover such as serum C-telopeptides (sCTX) skeletal isoenzymes of alkaline phosphatase for up to 5 years of treatment. Calcitonin (salmon) nasal spray results in a statistically significant 1-2% increase in lumbar spine Bone Mineral Density (BMD) which is evident from year 1 and is sustained for up to 5 years. Hip BMD is preserved

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 (osteitisde formans), Neurodystrophic disorders (synonymous with algo dystrophy 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: Gemitrol NS Nasal Spray is for intranasal use only. Gemitrol NS Nasal Spray delivers 200 IU calcitonin (salmon) per actuation.

CONTRAINDICATION: Hypersensitivity to synthetic calcitonin (salmon) or to any of the excipients of the formulation.Calcitonin is also contraindicated in patients with hypercalcemia..

WARNINGS & PRECAUTIONS:. Periodical nasal examinations with visualization of the nasal mucosa, turbinates, septum and mucosal blood vessel status are recommended. Nasal examinations should be performed before treatment begins and in the case of nasal complaints, medication should not be started. If severe ulceration of the nasal mucosa occurs (e.g. penetration below the mucosa or association with heavy bleeding), calcitonin (salmon) nasal spray should be discontinued. In case of mild ulceration, medication is to be interrupted temporarily until healing occurs. Because calcitonin is a peptide, the possibility of systemic allergic reactions exists and allergic type reactions including isolated cases of anaphylactic shock have been reported in patients receiving calcitonin (salmon) nasal spray. In patients with suspected sensitivity to calcitonin, skin testing should be considered prior to treatment. Allergic reactions should be differentiated from generalized flushing and hypotension. The excipient benzalkonium chloride solution is an irritant and may cause irritation of the nasal mucosa. Calcitonin (salmon) nasal spray may cause transient dizziness, which may impair the reaction of the patient. Patients must therefore be warned that transient dizziness may occur in which case they should not drive

or use machines.

DRUG INTERACTIONS: No drug interactions with intranasal calcitonin (salmon) have been reported. Concomitant use of calcitonin and lithium may lead to a reduction in plasma lithium concentrations. The dose of lithium may need to be adjusted.

ADVERSE REACTIONS: The most frequently observed undesirable effects are local reactions such as rhinitis and nasal discomfort. They are generally mild and rarely require discontinuation of the treatment Investigations: Development of neutralizing antibodies to calcitonin, Nervous system disorders: Dizziness, headache, dysgeusia., Eye disorders: Visual disturbance, Respiratory, thoracic and mediastinal disorders: 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, Gastrointestinal disorders: Nausea, diarrhoea, abdominal pain, Vomiting, Skin and subcutaneous tissue disorders: Pruritus, Rash generalized, Musculoskeletal and connective tissue disorders: Musculoskeletal pain including arthralgia, Vascular disorders: Flushing, Hypertension. General disorders and administration site conditions: Fatigue, Influenza-like symptoms, oedema (facial, extremities and generalized),Immune system disorders: Hypersensitivity reactions, Anaphylactic and anaphylactoid reactions such as tachycardia, hypotension, circulatory collapse and anaphylactic shock

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

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(Additional information is available on request)