The recommended dose offemales is one spray (200 I.U.) per day administered intranasally, alternating nostrils daily.Before the first dose and administration,Spray should be at room temperature. To prime the pump, the bottle should be held upright and the two white side arms of the pump depressed toward the bottle until a full spray is produced.

**Active Pharmaceuticals Ingredients Manufacturers** 



Taj Pharma PDI



# Taj Pharmaceuticals Ltd.

**Calcitonin** 

CAS No.: 47931-85-1

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H-2260-GMP, 4013234 Calcitonin powder CAS No. 47931-85-1 (net)

#### **Identifiers**

Symbols CALCA; CALC1; CGRP; CGRP-I; CGRP1; CT; KC; MGC126648

External IDs OMIM: 114130 MGI: 2151253 HomoloGene: 1319

H-Cys-Ser-Asn-Leu-Ser-Thr-Cys-Val-Leu-Gly-Lys-Leu-Ser-Gln-Glu-Leu-His-Lys-Leu-Gln-Thr-Tyr-Pro-Arg-Thr-Asn-Thr-Gly-Ser-Gly-Thr-Pro-NH2 acetate salt (Disulfide bond)

Fields of application

Osteoporosis

Hypercalcemia

Paget's disease

Reflex sympathetic dystrophy

(algodistrophy or Sudeck's disease)

Active substance

Calcitonin (salmon) positively influences bone mass density due to its inhibiting effect on osteoclast activity.

Also known as: Human calcitonin, Thyrocalcitonin

Formal name: Calcitonin

Related tests: RET oncogene, Calcium

H-Cys-Ser-Asn-Leu-Ser-Thr-Cys-Val-Leu-Gly-Lys-Leu-Ser-Gln-Glu-Leu-His-Lys-Leu-Gln-Thr-Tyr-Pro-Arg-Thr-Asn-Thr-Gly-Ser-Gly-Thr-Pro-NH<sub>2</sub>

Orthologs

Human Mouse

Entrez 796 12310

E 11 ENGC 000

Ensembl ENSG00000110680 ENSMUSG00000030669

Uniprot P01258 Q99JA0

Refseq NM 001033952 (mRNA)

NP\_001029124 (protein) NM\_001033954 (mRNA)

NP 001029126 (protein)

## SIDE EFFECTS

Minor adverse effects such as nasal irritation are seen in a small number of patients. Calcitonin does not reduce the serum calcium levels below normal in patients with postmenopausal osteoporosis. It may reduce the magnesium in some cases.

following adverse events were reported in fewer than 3% of patients during chronic therapy

Adverse events reported in 1%-3% of patients are identified with an asterisk(\*). The remainder occurred in less than 1% of patients. Other than flushing, nausea, possible allergic reactions, and possible local irritative effects in the respiratory tract, a relationship to Miacalcin® Nasal Spray has not been established.





# Calcitonin

CAS NO- 47931-85-1

Body as a whole — General Disorders: influenza-like symptoms\*, fatigue\*, periorbital edema, fever

Integumentary: erythematous rash\*, skin ulceration, eczema, alopecia, pruritus, increased sweating

Musculoskeletal/Collagen: arthrosis\*, myalgia\*, arthritis, polymyalgia rheumatica, stiffness

Respiratory/Special Senses: sinusitis\*, upper respiratory tract infection\*, bronchospasm\*, pharyngitis, bronchitis, pneumonia, coughing, dyspnea, taste perversion, parosmia

Cardiovascular: hypertension\*, angina pectoris\*, tachycardia, palpitation, bundle branch block, myocardial infarction

Gastrointestinal: dyspepsia\*, constipation\*, abdominal pain\*, nausea\*, diarrhea\*, vomiting, flatulence, increased appetite, gastritis, dry mouth

Liver/Metabolic: cholelithiasis, hepatitis, thirst, weight increase

Endocrine: goiter, hyperthyroidism

Urinary System: cystitis\*, pyelonephritis, hematuria, renal calculus

Central and Peripheral Nervous System: dizziness\*, paresthesia\*, vertigo, migraine, neuralgia, agitation

Hearing/Vestibular: tinnitus, hearing loss, earache

Vision: abnormal lacrimation\*, conjunctivitis\*, blurred vision, vitreous floater

Vascular: flushing, cerebrovascular accident, thrombophlebitis

#### **PRECAUTIONS**

A large and diverse set of effects has been attributed to calcitonin, but in many cases, these were seen in response to pharmacologic doses of the hormone, and their physiologic relevance is suspect. It seems clear however, that calcitonin plays a role in calcium and phosphorus metabolism. In particular, calcitonin has the ability to decrease blood calcium levels at least in part by effects on two well-studied target organs:

- \* Bone: Calcitonin suppresses resorption of bone by inhibiting the activity of osteoclasts, a cell type that "digests" bone matrix, releasing calcium and phosphorus into blood.
- \* Kidney: Calcium and phosphorus are prevented from being lost in urine by reabsorption in the kidney tubules. Calcitonin inhibits tubular reabsorption of these two ions, leading to increased rates of their loss in urine.

### **INTERACTIONS**

Formal studies designed to evaluate drug interactions with calcitonin-salmon have not been done. No drug interaction studies have been performed withcalcitonin-salmonNasal Spray ingredients. Currently, no drug interactions with calcitonin-salmon have been observed. The effects of prior use of diphosphonates in postmenopausal osteoporosis patients have not been assessed; however, in patients with Paget's Disease prior diphosphonate use appears to reduce the anti-resorptive response







#### **DRUG DESCRIPTION**

Calcitonin is a polypeptide hormone secreted by the parafollicular cells of the thyroid gland in mammals and by the ultimobranchial gland of birds and fish. It is provided in a 3.7 mL fill glass bottles as a solution for nasal administration. This is sufficient medication for at least 30 doses. Active Ingredient: calcitonin-salmon 2200 I.U. per mL (corresponding to 200 I.U. per 0.09 mL actuation).nactive Ingredients: sodium chloride, benzalkonium chloride, hydrochloric acid (added as necessary to adjust pH) and purified water.

Calcitonin is a 32-amino acid linear polypeptide hormone that is produced in humans primarily by the parafollicular cells (also known as C-cells) of the thyroid, and in many other animals in the ultimobranchial bodyIt acts to reduce blood calciumopposing the effects of parathyroid hormone (PTHIt has been found in fish,





reptiles, birds, and mammals. Its importance in humans has not been as well established as its importance in other animals, as its function is usually not significant to regulation of normal calcium homeostasis

#### DOSAGE

The recommended dose offemales is one spray (200 I.U.) per day administered intranasally, alternating nostrils daily. Before the first dose and administration, Spray should be at room temperature. To prime the pump, the bottle should be held upright and the two white side arms of the pump depressed toward the bottle until a full spray is produced. The pump is primed once the first full spray is emitted. To administer, the nozzle should be carefully placed into the nostril with the head in the upright position, and the pump firmly depressed toward the bottle. The pump should not be primed before each daily dose.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export \*\*\* subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

http://www.tajapi.com

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91 022 30601000.

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