Taj Pharmaceuticals Ltd.

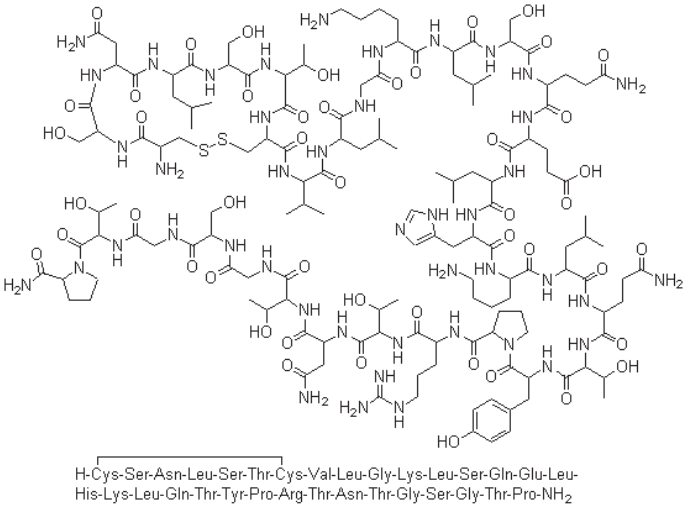
Calcitonin

CAS No. : 47931-85-1

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.



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_2

Also known as: Human calcitonin, Thyrocalcitonin
Formal name: Calcitonin
Related tests: RET oncogene, Calcium

Orthologs
Human Mouse
Entrez 796 12310
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.

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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

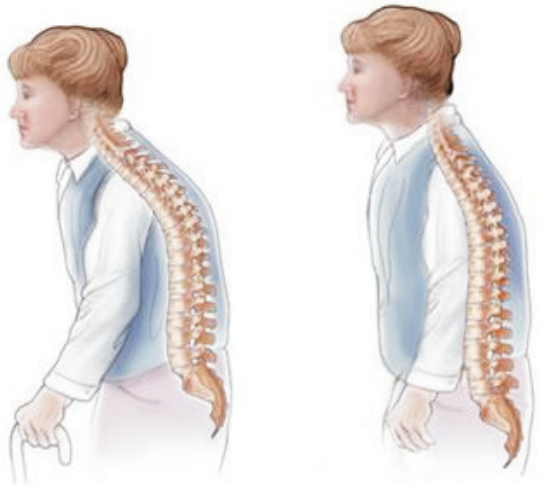
A large and diverse set of effects has been attributed to calcitonin, but in many cases, these were seen in response to pharmacologic doses of the hormone, and their physiologic relevance is suspect. It seems clear however, that calcitonin plays a role in calcium and phosphorus metabolism. In particular, 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.

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:
http://www.tajapi.com
or by contacting the sponsor, Taj Pharmaceuticals Limited., at:
91 022 30601000.
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