

Physician's Prescribing Information**SALCO 100 IU****COMPOSITION**

Each ampoule contains the active principle Synthetic Salmon Calcitonin 100 I.U.
List of excipients: Galcial acetic acid, Sodium acetate, Sodium chloride, Water for injections.

PHARMACEUTICAL FORM: Injection solution for intramuscular, intravenous use and subcutaneous.

THERAPEUTIC INDICATIONS:

- Paget's disease (osteitis deformans).
- Post menopausal osteoporosis.
- Hypercalcemia.

WARNINGS

Allergic reactions: because Calcitonin is protein in nature, the possibility of a systemic allergic reaction exists. Administration of Calcitonin Salmon has been reported in a few cases to cause serious allergic-type reactions (e.g., bronchospasm, swelling of the tongue or throat, and anaphylactic shock), and in one case, death attributed to anaphylaxis. The usual provisions should be made for the emergency treatment of such a reaction should it occur. Allergic reactions should be differentiated from generalized flushing and hypotension.

Skin testing should be considered prior to treatment with Calcitonin. The following procedure is suggested: prepare a dilution of 10 IU per ml by withdrawing 1/20 ml (0.05 ml) in a tuberculin syringe and filling it to 1.0 ml with Sodium Chloride Injection, USP. Mix well, discard 0.9 ml and inject intracutaneously 0.1 ml (approximately 11 I.U.) on the inner aspect of the forearm. Observe the injection site 15 minutes after injection. The appearance of more than mild erythema or wheal constitutes a positive response.

The incidence of osteogenic sarcoma is known to be increased in Paget's disease. Pagetic lesions, with or without therapy, may appear by X-ray to progress markedly, possibly with some loss of definition of periosteal margins. Such lesions should be evaluated carefully to differentiate these from osteogenic sarcoma.

CONTRAINDICATIONS: Individual hypersensitivity to Salmon Calcitonin.

PROPERTIES: Salco 100 IU is a synthetic salmon calcitonin. Calcitonin is one of the hormones, which controls calcium metabolism and interferes with the parathormone action. It considerably reduces calcium mobilization from bones, when there is a high mineral turnover. This effect leads to a reduction of the calcemia. Owing to its action reducing the phosphate, sodium and calcium renal reabsorption, Calcitonin increases the excretion of circulating or excessive calcium. It can be therefore useful in the Paget's disease, in metastatic osteolitis, as an osteoporotic syndrome adjuvant in the Vitamin D hyperdosing.

POSODOLOGY

Paget's disease, Sudeck's disease, Osteoporosis: 100 I.U. a day or every other day, administered by intramuscular or subcutaneous injection. In the case of objective and subjective symptomatology improvement, it is possible to take into account a 50 I.U. daily administration. If necessary, doses can be increased up to 200 I.U. a day.

Hypercalcemia: 5-10 I.U. for any kg body weight, administered through a slow intravenous injection in 2 to 4 doses within 24 hours or through a drop infusion in 500 ml of physiological solution within 6 hours. Intravenous infusion represents the most effective administration method and it should be always used in emergency or severe cases.

Treatment duration: In the case of the Paget's disease or of other chronic affections, therapy should be carried on for few months. Treatment highly reduces alkaline phosphatase plasma level and hydroxyproline urinary excretion up to normal level. Pain is partially or totally reduced. In rare cases, alkaline phosphatase and hydroxyproline excretion levels can increase after an initial fall. In such a case, the physician should judge on the basis of the clinical situation whether the therapy should be carried on or not. One or more months after the treatment interruption, bone metabolism disturbances may occur again and a new therapy cycle is needed.

PRECAUTIONS

General: the administration of Calcitonin possibly could lead to hypocalcemic tetany under special circumstances although no cases have yet been reported. Provisions for parental calcium administration should be available during the first several administration of Calcitonin.

Laboratory tests: periodic examinations of urine sediment of patients on chronic therapy are recommended.

Coarse granular casts and casts containing renal tubularepithelial cells were reported in young adult volunteers at bed rest who were given Calcitonin Salmon to study the effect of immobilization on osteoporosis. There was no other evidence of renal abnormality and the urine sediment became normal after Calcitonin was stopped. Urine sediment abnormalities have not been reported by other investigators.

Instructions for the Patient: careful instructions in sterile injection technique should be given to the patient, and to other persons who may administer Salco 100 IU Injection.

Long term treatment for bed-ridden patients should be combined by a monthly check of the biochemical blood and renal function.

Salco 100 IU should not be administered in case of ascertained or presumed pregnancy or during breast-feeding.

Salco 100 IU should not be administered to children for more than some weeks, unless the physician asks for it owing to really severe medical reasons. Some patients could develop antibodies to Calcitonin after prolonged treatment. Such antibodies development generally is of low level and occurs with high dosages. Besides it is not generally linked to a clinical efficacy worsening. It is possible that such a phenomenon is similar to what happens in the cases of diabetic patients, who frequently develop antibodies to insulin, but rarely show a clinical insulin resistance.

SIDE EFFECTS: Nausea, vomiting, slight flushing of the face combined to a heat sensation. Such phenomena are generally linked to dosage and they appear more frequently after intravenous administration than after intramuscular or subcutaneous administration. They usually disappear spontaneously and only in exceptional cases require for a temporary dosage decrease. Sometimes, inflammatory reactions can appear on the injection site. Following hyperdosing, it is theoretically possible that calcemia decreases up to tetany hypocalcemia onset. Would it be the case, calcium should be administered.

INTERACTIONS WITH DIFFERENT DRUGS: No interaction is known.

PACKAGE: 5 Calcitonin ampoules (1 ml) of 100 I.U. each.

STORAGE: Keep at a temperature between 2°C – 8°C and protect from the light. KEEP OUT OF THE REACH OF CHILDREN.

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Manufacturer: Laboratorio Italiano Biochimico Farmaceutico LISAPHARMA S.p.A., Italy

Importer: Genmedix Ltd., P.O.B. 8500, Netanya 42504

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