CLASTEON 400 mg hard capsules

Clodronic acid

PHARMACOTHERAPEUTIC CATEGORY
Drugs for the treatment of bone diseases - Drugs affecting bone structure and mineralization - bisphosphonates

THERAPEUTIC INDICATIONS
- Tumor osteolysis
- Multiple myeloma
- Primary hyperparathyroidism
- Prevention and treatment of postmenopausal osteoporosis

CONTRAINDICATIONS
Hypersensitivity to the active substance (clodronic acid), or to any other drug of the bisphosphonate class or to any other excipient;

PRECAUTIONS FOR USE
The ingestion of foods containing large amounts of calcium (milk, cheese, etc.) must be done at least 2-3 hours after the assumption of the product. For the same reason, in case of oral administration, the intake of medicines containing divalent ions (such as Ca++, Mg++, etc.) must be avoided during the first 2-3 hours after the treatment with the product. Since the product is mainly eliminated through the kidneys, it's advisable to proceed with extreme caution in the treatment of patients affected by renal failure, particularly when the product is administered intravenously. In such cases the use of clodronate must be decided only after a thorough risk/benefit analysis and a frequent monitoring of the kidney function indicators.

INTERACTIONS
Calcium and other divalent cations may interact with the clodronic acid, forming non bioavailable complexes. Therefore, in case of oral administration, the intake of other medicines containing divalent ions (such as Calcium and Magnesium) shall be avoided during the 2-3 hours after the treatment with CLASTEON.

SPECIAL WARNINGS
Osteonecrosis of the jaw, generally associated with tooth extraction and/or local infection (including osteomyelitis), has been reported in patients with cancer who are receiving treatment regimens including primarily intravenously administered bisphosphonates. Many of these patients were also receiving chemotherapy and corticosteroids. Osteonecrosis of the jaw has also been reported in patients with osteoporosis receiving oral bisphosphonates. A dental examination with appropriate preventive dentistry should be considered prior to treatment with bisphosphonates in patients with concomitant risk factors (e.g. cancer, chemotherapy, radiotherapy, corticosteroids, poor oral hygiene, periodontal disease). While on treatment, these patients should avoid invasive dental procedures if possible. For patients who develop osteonecrosis of the jaw while on bisphosphonate therapy, dental surgery may exacerbate the condition. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces the risk of osteonecrosis of the jaw. Clinical judgement of the treating physician should guide the management plan of each patient based on individual benefit/risk assessment

Pregnancy and lactation
There are no satisfactory data available regarding the use of clodronic acid in pregnant women. CLASTEON must not be used during pregnancy unless in case of absolute necessity. It is not known whether the clodronic acid is excreted into the mother's milk. In case of treatment on a lactating woman, it is necessary to decide whether to discontinue the lactation or the treatment with CLASTEON, assessing the benefit of the maternal milk for the baby and the benefit of the treatment for the mother. Ask your attending doctor before taking any medicine.

DOSES AND METHOD OF ADMINISTRATION

Tumor Osteolysis, Multiple myeloma, Primary Hyperparathyroidism
The following posological scheme must be considered as a general guide and it can be therefore adjusted according to the needs of the patient. 1-6 capsules a day, divided into 2-3 administrations, to be taken on an empty stomach, for 3-4 weeks. Such cycles can be repeated at varying intervals depending on the development of the disease. The periodical assessment of the bone resorption parameters may be useful in guiding the cycles of therapy.

Prevention and treatment of postmenopausal osteoporosis
The posology can vary as follows according to the clinical picture and the and mineralometric values: From 1 capsule a day for a 30 day therapy, followed by 60 days of discontinuation (repeated for more cycles). Up to 1 capsule a day for a 1 year nonstop therapy, or longer, according to the patient's conditions. It is advisable to take the medication at least 1 hour before breakfast or the main meals with abundant water.

OVERDOSE
Although there is no experience of overdosing with clodronic acid, it is theoretically possible that large amounts of product may induce hypocalcemia. In such cases the treatment shall correct the hypocalcemia by administration of a adequate food supplements or, in more severe cases, by IV administration of calcium. In case of alteration of the kidney function due to the formation of calcium aggregates, the therapy shall aim to restoring the function. In case of accidental ingestion/assumption of an excessive dose of CLASTEON, report immediately to the attending physician or go to the closest hospital.

IN CASE OF ANY DOUBT ON THE USE / TREATMENT WITH CLASTEON, PLEASE CONTACT YOUR DOCTOR UNDESIRABLE EFFECTS
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The use of a high dosage of the product may cause light gastrointestinal disorders. As all medicines, CLASTEON may cause undesirable effects, although not every patient show them. If any of the undesirable effects worsen, or if you notice the occurrence of any undesirable effect that in not reported on the information leaflet, please inform your doctor.

EXPIRY AND STORAGE
Keep CLASTEON away from the reach and the sight of children. Do not use CLASTEON after the date of expiry reported on the package. The date of expiry refers to the last day of the month. Medicines must not be disposed of in the wastewater or in the domestic waste. Ask your pharmacist how to dispose of expired medicines. This will help to protect the environment.

COMPOSITION
Clasteon 400 mg hard capsules
Each capsule contains:
Active substance
Disodium clodronate 400 mg
Excipients
Sodium starch glycolate (type A), maize starch, talc, magnesium stearate
Components of the sheath
Gelatin, titanium dioxide (E171), indigotin (E132).

PHARMACEUTICAL FORM AND CONTENT
CLASTEON 400 mg hard capsules Hard capsules in PVC/PVDC Blister containing 10 capsules

MARKETING AUTHORIZATION HOLDER
ABIOGEN PHARMA S.p.A.
Via Meucci 36 - Ospedaletto - PISA

MANUFACTURER AND FINAL CONTROLLER
ABIOGEN PHARMA S.p.A.
Via Meucci 36 - Ospedaletto - PISA

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THIS IS A MEDICAMENT

- A Medicament is a product, which affects your health, and its consumption, contrary to instruction, is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not, by yourself, interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of the reach of children

NEWBRIDGE PHARMACEUTICALS