Eladynos® (Abaloparatide) ▼Prescribing Information

Please refer to the Summary of Product Characteristics for other adverse reactions before prescribing

Presentation: Eladynos 80 micrograms/dose solution for injection in a pre-filled pen. Each dose of 40 microliters contains 80 micrograms of Eladynos. Each pre-filled pen contains 3 mg of abaloparatide in 1.5 mL of solution (corresponding to 2 milligrams per mL). **Indication:** Treatment of osteoporosis in postmenopausal women at increased risk of fracture. **Dosage and administration:** The recommended dose is 80 micrograms once daily, for subcutaneous use only. Eladynos should be injected in the lower abdomen. The site of the injection should be rotated every day. Injections should be administered at approximately the same time every day. The first injection(s) administered by the patient or caregiver should be performed under the guidance of an appropriately qualified health care professional. Patients and/or caregivers should be trained in the subcutaneous administration of Eladynos. A detailed instruction for use is included in each pack to instruct patients on the correct use of the injection pen. The maximum total duration of treatment with Eladynos should be 18 months. Patients should receive supplemental calcium and vitamin D if dietary intake is inadequate. Following cessation of Eladynos therapy, patients may be continued on other osteoporosis therapies such as bisphosphonates. **Dosing in special populations - *Elderly patients:*** Dose adjustment based on age is not required. ***Renal impairment:*** Eladynos must not be used in patients with severe renal impairment including patients with end-stage renal disease. In patients with mild to moderate renal impairment, dose-based adjustment is not required. ***Hepatic impairment:*** No data are available in patients with impaired hepatic function. Dose adjustment is not required for these patients, as it is unlikely that hepatic impairment will have a significant effect on Eladynos exposure. ***Paediatric population*:** Eladynos should not be used in children and adolescents less than 18 years because of safety concerns. ***Missed dose**:* If a patient forgets or cannot administer their dose at the usual time, it can be injected within 12 hours of the normally scheduled time. Patients should not administer more than one injection in the same day and should not try to make up for a missed dose. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients listed in the SmPC, pregnancy and breast-feeding, women of childbearing potential, pre-existing hypercalcaemia, severe renal impairment, unexplained elevations of serum alkaline phosphatase, patients with known risks for osteosarcoma such as those who have received prior external beam or implant radiation therapy involving the skeleton and patients with skeletal malignancies or bone metastases. **Special warnings and precautions for use: *Orthostatic hypotension and increased heart rate*:** Orthostatic hypotension and transient episodes of increase in heart rate may occur with Eladynos, typically within 4 hours of injection. Symptoms may include dizziness, palpitations, tachycardia, or nausea, and may resolve by having the patient lie down. The first injection(s) of Eladynos should be performed under the guidance of an appropriately qualified health care professional who may observe the patient during the first hour after injection. Eladynos should always be administered where the patient can sit or lie down if necessary. Eladynos may have a vasodilating effect on vascular smooth muscle and positive chronotropic/inotropic effects on cardiac muscle. Individual benefit risk assessment is important. Blood pressure, cardiac status and ECG should be assessed prior to beginning treatment with Eladynos. Patients with cardiac disease should be monitored for worsening of their disease. If severe orthostatic hypotension or severe cardiovascular symptoms occur, the treatment should be discontinued. ***Hypercalcaemia***: In normocalcaemic patients, transient elevations of serum calcium concentrations have been observed following Eladynos injection. Serum calcium concentrations reach a maximum at approximately 4 hours and return to baseline by 24 hours after each dose. Therefore, if blood samples for serum calcium measurements are taken, this should be done approximately 24 hours after the most recent injection. Routine calcium monitoring during therapy is not required in patients without additional risk factors for hypercalcaemia. ***Hypercalciuria and urolithiasis***. Eladynos may cause hypercalciuria. It is unknown whether Eladynos may exacerbate urolithiasis in patients with active or a history of urolithiasis. If active urolithiasis or pre-existing hypercalciuria is suspected, measurement of urinary calcium excretion should be considered. ***Duration of treatment***: The maximum total duration of treatment with Eladynos should be 18 months. Studies in rats indicate an increased incidence of osteosarcoma with long-term administration of Eladynos. ***Sodium content:*** This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium free'. **Interaction with other medicinal products and other forms of interaction:** No dedicated clinical drug-drug interaction studies have been performed with Eladynos. The interaction potential of Eladynos is regarded low considering its pharmacokinetic properties. There is no data on efficacy of Eladynos in patients with prior or concomitant bisphosphonate or glucocorticoid treatment. Concomitant use of vasoactive medicinal products may predispose to orthostatic hypotension since the blood pressure lowering effect of Eladynos may be increased. Sporadic case reports have suggested that hypercalcaemia may predispose patients to digitalis toxicity. Because Eladynos has been shown to increase serum calcium, it should be used with caution in patients taking digitalis. **Fertility, pregnancy and lactation**: Eladynos is not indicated in women of childbearing potential. It is not to be used in women who are, or may be, pregnant or breast-feeding. ***Pregnancy***: Eladynos is contraindicated during pregnancy. ***Breast-feeding:*** It is unknown whether Eladynos is excreted in human milk. A risk to the newborns/infants cannot be excluded. Eladynos is contraindicated during breast-feeding. ***Fertility:*** No data are available on the effect of Eladynos on human fertility. Studies in rats with Eladynos have shown no effects on male fertility. **Effects on ability to drive and use machines:** Eladynos has no or negligible influence on the ability to drive and use machines. Transient orthostatic hypotension or dizziness may occur following administration of Eladynos. These patients should refrain from driving or the use of machines until symptoms have subsided. **Side effects: *Very Common (≥1/10):*** Dizziness, hypercalciuria. ***Common (≥1/100 to <1/10):*** Hypercalcaemia, hyperuricaemia, insomnia, headache, palpitations, tachycardia, hypertension, nausea, abdominal pain, constipation, diarrhoea, vomiting, pruritus, rash, back pain, arthralgia, pain in extremity, muscle spasms (back and legs), bone pain, nephrolithiasis, injection site reaction, fatigue, asthenia and malaise. ***Uncommon (≥1/1000 to <1/100):*** Hypersensitivity, orthostatic hypotension, abdominal distension and pain. **Package Quantities & Cost:** Solution for injection:1 pre-filled pen of 1.5 mL solution. *£294.54.* **Marketing authorisation numbers:** EU/1/22/1706/001, EU/1/22/1706/002**,** PLGB 49876/0025. **Marketing authorisation holder**: Theramex Ireland Limited, 3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1, D01 YE64, Ireland. **Legal classification:** POM **Date of Preparation:** ELAD_UK_EN_16936_v3, November 2024. This medicinal product is subject to additional monitoring.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellowcard in the Google Play or Apple App store.
Adverse events should also be reported to Theramex on medinfo.uk@theramex.com or Tel: 0333 0096795