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Direct Healthcare Professional Communication
Calcitonin associated with malignancy - new restrictions on use and withdrawal of the nasal spray dosage form from the market

Dear Healthcare Professional,

The Saudi Food and Drug Authority (SFDA) has recently completed a review of the benefits and risks of calcitonin, this review showed an increased risk of malignancies with long term calcitonin use compared with placebo treated patients.

Due to the higher incidence of malignancies, the following were concluded:

- Calcitonin should no longer be used in the treatment of established post-menopausal osteoporosis, since the risks associated with calcitonin outweigh its benefits in this indication.
- Patients being treated for osteoporosis with calcitonin should switch to alternative treatment during the next scheduled (or routine) appointment.

The benefits of calcitonin continue to outweigh the risks in the short term treatment of:

- Paget's disease only in patients who do not respond to alternative treatments or for whom such treatments are not suitable, e.g. in patients with severe renal impairment. Treatment in this indication should be limited in most cases to 3 months.
- Hypercalcaemia of malignancy.

The treatment with calcitonin should be limited to the shortest time and the lowest dose possible for all indications.

It was also concluded that Miacalcic nasal spray, which was authorized only for the treatment of post-menopausal osteoporosis, **will be withdrawn from the market**, and calcitonin will only be available as a solution for injection to treat above approved indications.

The letter is sent in agreement with the Saudi Food and Drug Authority.

Call for Reporting

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Sincerely,

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