

MINISTRY OF HEALTH & MEDICAL EDUCATION

IRAN FOOD & DRUG ADMINISTRATION

Date: 24-May-2022

Dear IFDA,

Amgen would like to notify you about the MHRA publication on their website related to Prolia and the risk of serious hypercalcaemia in patients under 18 years. Denosumab 60mg (Prolia) should not be used in patients under 18 years due to the risk of serious hypercalcaemia.

Please find below the full published article on the MHRA website:

<https://www.gov.uk/drug-safety-update/denosumab-60mg-prolia-should-not-be-used-in-patients-under-18-years-due-to-the-risk-of-serious-hypercalcaemia>

Article citation: Drug Safety Update volume 15, issue 10: May 2022: 1.

Amgen intends to submit this update as safety variation in the Irani market by Q3'2022 to add this recommendation in local SmPC & PIL based on EU reference label v93 approved by CHMP on 5th May 22.

Should you have any questions or require additional information, please feel free to contact us.

Thank you for your cooperation.

Yours faithfully,

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