PLEASE READ

IMPORTANT MEDICINE SAFETY INFORMATION

APPROVED BY THE HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Introduction of risk minimisation educational materials for Denosumab 60 mg injection:

▼ Conexxence, Evfraxy, Izamby, Jubbonti, Junod, Obodence, Osvyrti, Stoboclo and Zadenvi (denosumab)

24th November 2025

Dear Healthcare Professional,

Marketing authorisation holders of denosumab, in agreement with the Health Regulatory Authority (HPRA), wish to inform you of the availability of important risk minimisation educational materials for Conexxence, Evfraxy, Izamby, Jubbonti, Junod, Obodence, Osvyrti, Stoboclo and Zadenvi (Denosumab).

Please find enclosed the following:

- **Patient Reminder Cards - 3 copies**

Patients Reminder Card

Objectives:
Patient reminder cards are being provided to highlight the risk of osteonecrosis of the jaw (ONJ) during and after treatment with denosumab, and to remind patients to tell their doctor of important symptoms that may suggest that they have developed ONJ.

Rationale for the additional risk minimisation activity:
The purpose of the patient reminder card is to remind patients about important safety information that they need to be aware of before and during treatment with denosumab injections for osteoporosis and bone loss, including:

- the risk of osteonecrosis of the jaw during treatment with denosumab;
- the need to highlight any problems with their mouth or teeth to their doctors/nurses before starting treatment;
- the need to ensure good oral hygiene during treatment;
- the need to inform their dentist of treatment with denosumab and to contact their doctor or dentist if problems with the mouth or teeth occur during treatment.

Please provide your patients/their caregivers with the Patient Reminder Card (if appropriate) and ensure they understand the material prior to treatment with denosumab.

Please cascade this letter and accompanying educational materials to the relevant members of your team.

If you need additional information or would like to request additional copies of the patient reminder card, please contact the relevant Marketing Authorisation Holder from Table 1 below.

Electronic versions of the Patients Reminder Card are also available on www.hpra.ie (enter 'denosumab' in the 'Find a medicine' search box and click on 'EdM' next to any of the above mentioned 'denosumab' products).
The most up to date SmPC and PIL can be accessed via the HPRA website www.hpra.ie.

Call for reporting

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions via: HPRA Pharmacovigilance. Website: www.hpra.ie.

Company contact point

Suspected adverse reactions should also be reported to the relevant Marketing Authorisation Holders (see contact details below in Table 1).

Table 1

Marketing Authorisation Holder	Product Licence Number	Product Name	Email	Telephone
Accord Healthcare S.L.U	EU/1/25/1922/002	Osvyrti (denosumab)	To order more materials - medinfo@accord-healthcare.com To report suspected adverse reactions - medinfo@accord-healthcare.com	+44 (0) 1271 385 257
Biosimilar Collaborations Ireland Limited	EU/1/25/1946/001	Evfraxy (denosumab)	To order more materials - medical.informationEU@biocon.com To report suspected adverse reactions - medical.informationEU@biocon.com	1800 777794
Celltrion Healthcare Hungary Kft.	EU/1/24/1905/001	Stoboclo (denosumab)	To order more materials - Enquiry_IE@celltrionhc.com To report suspected adverse reactions - medinfoie@celltrionhc.com	01 223 4026 01 564 5074
Fresenius Kabi Deutschland GmbH	EU/1/25/1954/001	Conexxence (denosumab)	To order more materials - medical.information-uk@fresenius-kabi.com To report suspected adverse reactions - pharmacovigilance.GB@fresenius-kabi.com	+44 (0) 1928 533 533 +44 (0) 800 090 2513
Gedeon Richter Plc	EU/1/25/1933/001	Junod (denosumab)	To order more materials - Drugsafety.uk@gedeonrichter.eu To report suspected adverse reactions - Drugsafety.uk@gedeonrichter.eu	+44 (0)207 604 8806
mAbxience Research S.L	EU/1/25/1935/001	Izamby (denosumab)	To order more materials - pharmacovigilance@mabxience.com To report suspected adverse reactions - pharmacovigilance@mabxience.com	-

Samsung Bioepis NL B.V.	EU/1/24/1890/001	Obodence (denosumab)	To order more materials - sb.armm@samsung.com To report suspected adverse reactions bioepis.mi@medinformation.co.uk	1800 441 100
Sandoz GmbH	EU/1/24/1813/001	Jubbonti (denosumab)	To order more materials - mi.ireland@sandoz.net To report suspected adverse reactions - adverse.event.ireland@sandoz.net	+353 2750077
Zentiva k.s.	EU/1/25/1937/001	Zadenvi (denosumab)	To order more materials - UKMedInfo@zentiva.com To report suspected adverse reactions - UKMedInfo@zentiva.com	+353 818882243

Yours sincerely,

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Margo Broderick
Regulatory Manager PV & NP
Accord Healthcare Ireland Ltd.

Signed on behalf of the Marketing Authorisation Holders listed the table above.