

Please read the package leaflet that comes with your medicine for further information.

BBBC2244

▼ **This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.**

**Reporting of side effects: If you get any side effects, talk to your doctor, pharmacist or nurse.**

**You can report side effects directly via:**

**HPRA Pharmacovigilance.**

**Website: [www.hpra.ie](http://www.hpra.ie)**

**By reporting side effects, you can help provide more information on the safety of this medicine.**

▼ **Denosumab 120 mg injection**

Patient Card

**This reminder card contains important safety information that you need to be aware of before and during treatment with denosumab injections for cancer-related conditions**

**Date of HPRA Approval:** October 2025

**Version 1: Date of Preparation:** October 2025

Your doctor has recommended that you receive denosumab injections to help prevent bone complications (e.g. fractures) caused by bone metastases, or bone cancers.

A side effect called osteonecrosis of the jaw (ONJ, bone damage in the jaw) has been reported commonly (may affect up to 1 in 10 people) in patients receiving denosumab injections for cancer-related conditions. ONJ can also occur after stopping treatment.

It is important to try to prevent ONJ developing as it may be a painful condition that can be difficult to treat. In order to reduce the risk of developing ONJ, there are some precautions you should take:

#### **Before starting treatment:**

- Check with your doctor whether a dental examination is recommended before you start treatment with denosumab.
- Tell your doctor/nurse (health care professional) if you have any problems with your mouth or teeth.

Patients undergoing dental surgery (e.g. tooth extractions), who do not receive routine dental care or have gum disease, are smokers, of older age, who get different types of cancer treatments may have a higher risk of developing ONJ.

#### **While being treated:**

- You should maintain good oral hygiene and receive routine dental check-ups. If you wear dentures you should make sure these fit properly.
- If you are under dental treatment or will undergo dental surgery (e.g. tooth extractions), inform your doctor and tell your dentist that you are being treated with denosumab.
- Contact your doctor and dentist immediately if you experience any problems with your mouth or teeth such as loose teeth, pain or swelling, non-healing of sores or discharge, as these could be signs of ONJ.

## Denosumab RMM Patient Alert Card - Ireland

approved for print/date

**Mock-up**

**Proof Round**

**7**

### Item number: BBBC2244

**Originator:** NM

**Origination Date:** 08/04/2025

**Revision Date:** 25/09/2025

**Revised By:** SA

**Dimensions:** 255x55mm (85x55)

**Min Body Text Size:** 8pts

**Supplier:** N/A

**Technical** Date sent: N/A

**Approval** Date received:

### Colours

1. Black ●

2.

3.

4.

5.

6.

### Non Printing Colours

1. Profile ●

2.

3.

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**accord**

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