**Patient Reminder Card – Denosumab (Kefdensis)**

**This patient reminder card contains important safety information that you need to know before and during treatment with denosumab (Kefdensis).**

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

Your doctor has recommended that you receive denosumab (Kefdensis), which is used to treat osteoporosis and bone loss. These diseases cause the bones to break down and weaken, making them more prone to fracture. An adverse reaction known as osteonecrosis of the jaw (ONJ; damage to the jaw bone) has been reported rarely (may affect up to 1 in 1,000 people) in patients receiving Kefdensis due to osteoporosis. Osteonecrosis of the jaw can also occur after the end of therapy. It is important to try to prevent osteonecrosis of the jaw from developing, as it is a painful condition that can be difficult to treat. To reduce the risk of developing osteonecrosis of the jaw, you should follow a few precautions.

**Before starting treatment:**
Tell your doctor/healthcare professional if you have any problems with your mouth or teeth.
Your doctor may ask you to have a dental examination if you:

- have previously been treated with another medication, a bisphosphonate
- taking medication known as corticosteroids (such as prednisolone or dexamethasone)
- are a smoker
- suffer from cancer
- have not had a dental examination for a longer period of time
- have problems with your mouth or teeth

**During the treatment:**

- You should maintain good oral hygiene and have routine dental check-ups. If you wear dentures you should make sure these fit properly
- If you are undergoing dental treatment or a surgical dental procedure (e.g. tooth extractions), inform your doctor and tell your dentist that you are being treated with Kefdensis.
- Please contact your doctor and dentist immediately if you notice any problems with your mouth or teeth, such as loose teeth, pain or swelling, non-healing sores or discharge, as these could be signs of osteonecrosis of the jaw.

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

**Reporting of side effects**
The reporting of side effects is of great importance for the continuous monitoring of the benefit-risk ratio of medicinal products. Please report adverse reactions to:

- The **Malta Medicines Authority's ADR Reporting Website:** https://medicinesauthority.gov.mt/adrportal OR
- To the local distributor in Malta: **Pharma.mt Ltd** (Postal address: 21/22, Sqaq tal-Gidi o/ Valletta Road, Luqa, LQA 1771; email address: pharmacovigilance@pharmamt.com; telephone number: **+356 7953 4913**).

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

**Malta Medicines Authority Approval: December 2025**