

Email: postlicensing.medicinesauthority@gov.mt.

You may also report side effects to:
Mint Health Ltd, 3/4 Cantrija Complex,
Triq it-Targa, Il-Maghtab, Naxxar NXR6613 Malta

Telephone: +356 2093 9800

Email: pharmacovigilancemt@mint.com.mt.

By reporting side effects you can help provide more information on the safety of Stoboclo®.

Date of approval by Malta Medicines Authority: 16th March 2026



▼ (Denosumab) Patient Card

This card contains important safety information that you need to be aware of before and during treatment with denosumab (Stoboclo®).

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get.

Your doctor has recommended that you receive denosumab (Stoboclo®), which is used to treat osteoporosis and bone loss. These diseases involve thinning and weakening of the bones so they may break more easily.

An side effect called osteonecrosis of the jaw (ONJ) (bone damage in the jaw) has been reported rarely (may affect up to 1 in 1,000 people) in patients receiving Stoboclo® for osteoporosis. 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:

Tell your doctor/nurse (health care professional) if you have any problems with your mouth or teeth.

Your doctor may ask you to undergo a dental examination if you:

- were previously treated with another medication being a bisphosphonate
- are taking medicines called corticosteroids (such as prednisolone or dexamethasone)
- are a smoker
- have cancer
- have not had a dental check up for a long time
- have problems with your mouth or teeth

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 (Stoboclo®).

- Contact your doctor and dentist immediately if you experience any problems with your mouth or teeth such as loose teeth, pain or swelling, or non-healing of sores or discharge, as these could be signs of ONJ.

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can report side effects directly via Malta Medicines Authority ADR reporting form which is available online at: <https://medicinesauthority.gov.mt/adrportal>

and by post or email to:

Post: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000, Malta.