ZENTIVA

Patient reminder card

ZADENVI 60 mg solution for injection in pre-filled syringe (denosumab biosimilar)

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

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

A 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 denosumab 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 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.

- 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 osteonecrosis of the jaw

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 or pharmacist. This includes any possible side effects not listed in the information leaflet that comes in the pack. Suspected adverse reactions may also be reported to the Kosovo Agency for Medicinal Products and Medical Devices (KAMPM).

Electronically:	info@akkpm-rks.gov
By mail:	phv.akppm@rks-gov.net Kosovo Agency for Medicinal Products and Medical Devices (KMA) Hospital Circle, n.n. (UCCK), 10000 Prishtina, Kosovo
By fax:	+383 38 512 243

You may also report suspected adverse reactions to the Marketing Authorisation Holder (MAH) in Kosovo.

Contact details of the local qualified person responsible for pharmacovigilance on behalf of the Marketing Authorisation Holder:

Tringa Rraci, MPharm
Local Person Responsible for Pharmacovigilance (LPPV)
MAH Zentiva Pharma GmbH
Pharmakos LLC

Tel:	+383 49 621 621
E-mail:	pharmacovigilance@pharmakos.biz PV-Kosovo@zentiva.com

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

Kind regards,

Signature: _____

Tringa Rraci, Local Resposnible person for Yentiva Pharma GmbH, Germany