Patient reminder card regarding osteonecrosis of the jaw

This reminder card contains important safety information that you need to be aware of before and during treatment with Aclasta (zoledronic acid).

Your doctor has recommended that you receive Aclasta (zoledronic acid), which is used to treat post-menopausal women and adult men with osteoporosis or osteoporosis caused by treatment with steroids, and Paget's disease of the bone in adults. These diseases involve thinning and weakening of the bones so they may break more easily.

A side effect called osteonecrosis of the jaw (ONJ) (severe bone damage in the jaw) has been reported very rarely in patients receiving zoledronic acid for osteoporosis. ONJ can also occur after stopping treatment.

It is important to try and prevent ONJ developing as it is 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, brush your teeth regularly 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 zoledronic acid
- 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

Marketing Authorisation Holder: Novartis Europharm Limited, Frimley Business Park, Camberley GU16 7SR, United Kingdom.

Suspected adverse reactions and medication errors associated with the use of ACLASTA should be reported to:
Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gzira GZR 1386, or at:
www.medicinesauthority.gov.mt/adrportal

Alternatively at: Novartis Pharma Services Inc. Representative Office Malta by phone on 21222872.

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