

Annex

Conditions or restrictions with regard to the safe and effective use of the medicinal product to be implemented by the member states

Medicinal product no longer authorised

Conditions or restrictions with regard to the safe and effective use of medicinal product to be implemented by the member states

The Member States should ensure that all conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented:

The Marketing Authorisation Holder (MAH) shall provide an educational programme targeting all physicians who are expected to prescribe/use Zoledronic acid Teva Pharma for the treatment of osteoporosis prior to the launch in Member States. The MAH must agree the content and format of the educational material, together with a communication plan, with the national competent authorities in Member States prior to distribution of the educational programme.

The educational programme contains the following:

- Physician educational material
- Patient educational material

The physician educational material should contain the following key messages:

- Need to measure serum creatinine before treatment with Zoledronic acid Teva Pharma
- Contraindication in patients with creatinine clearance < 35 ml/min
- Contraindication in pregnancy and in breast-feeding women due to potential teratogenicity
- Need to ensure appropriate hydration of the patient
- Need to infuse Zoledronic acid Teva Pharma slowly over a period of no less than 15 minutes
- One-yearly dosing regime
- That all patients should be provided with the educational material and be counselled about:
 - Need for adequate calcium and vitamin D supplementation, appropriate physical activity, non-smoking and healthy diet
 - Key signs and symptoms of serious adverse events
 - When to seek attention from the health care provider

The patient educational material should contain the following key messages:

- Contraindication in pregnancy and in breast-feeding women
- Need for adequate calcium and vitamin D supplementation, appropriate physical activity, non-smoking and healthy diet
- Key signs and symptoms of serious adverse events
- When to seek attention from the health care provider