Safety Notice 013/22

Issue date
28 September 2022

Distributed to:
Chief Executives
Directors of Clinical Governance
Director, Regulation and Compliance Unit

Action required by:
Chief Executives
Directors of Clinical Governance

We recommend you also inform:
Directors, Managers and Staff of:
- Pharmacy
- Medical Services
- Nursing
- Hospital in the Home
- Ambulatory Care
- Endocrinology
- Cancer Services

Expert Reference Group
Content reviewed by:
Medication Safety Expert Advisory Committee

Clinical Excellence Commission
Tel: 02 9269 5500
Email
Internet Website
Intranet Website

Review date
February 2023

Packaging error – Zoledronic acid (Osteovan®) solution for injection vial

NSW Health has been alerted to an error on the packaging of zoledronic solution for injection 5 mg/100 mL vial, Osteovan brand. This product is a 'ready to infuse' solution. The outer packaging (box) and vial have been incorrectly labelled with 'Reconstitute and dilute before use'. There have been no reports of this error causing actual patient harm.

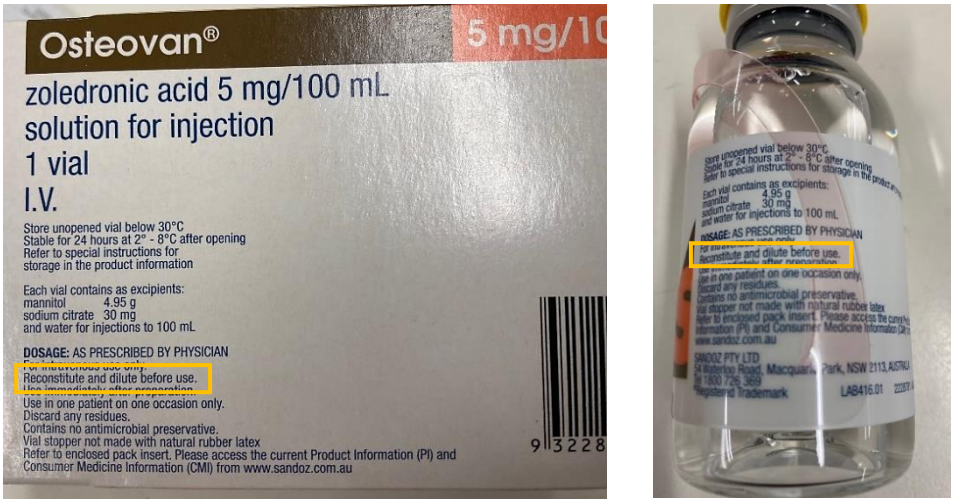

Figure 1. Affected product with incorrect information highlighted

The medicine is presented in a transparent plastic vial containing 100 mL of a clear, colourless solution that **does not require further reconstitution and dilution prior to administration.** The Product Information also provides the correct administration information and specifies Osteovan® as a 'ready to infuse' solution.

The drug sponsor has been notified and are taking steps to rectify the error on subsequent batches. A Dear Health Care Professional letter will be distributed shortly.

Required actions for Local Health Districts/Speciality Health Networks

1. Distribute this Safety Notice to all relevant clinicians and clinical departments where zoledronic acid is prescribed, dispensed and administered.
2. Identify clinical areas where this product may already be held and return all stock to the Pharmacy Department. **Stock should not be held in clinical areas (i.e., on 'imprest') until the packaging error has been rectified.**
3. Ensure vials and outer packaging are appropriately over-labelled and/or include additional information on the dispensing label e.g., further reconstitution and dilution **not** required prior to administration.
4. Ensure a system is in place to document actions taken in response to this Safety Notice.
5. Report any incidents associated with this packaging error into the local incident management system and to the TGA.
6. **Within 72 hours**, confirm receipt of this notice to: CEC-MedicationSafety@health.nsw.gov.au