

Teriparatide prefilled pens and cartridges: multidose formulations as a source of medication errors

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INTRODUCTION

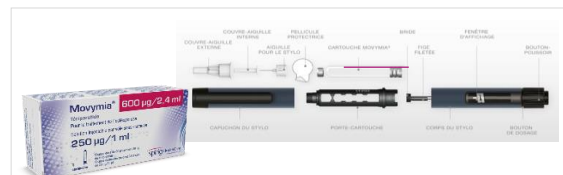
Teriparatide: recombinant human parathyroid hormone analog (rhPTH (1-34)) approved for the treatment of osteoporosis in patients at high risk of fracture

- the **only injectable drug (subcutaneous route) administered once daily in this indication currently**

- multidose formulations** (28 doses of 20 µg)



Prefilled pens
FORSTEO®, LIVOGIVA®, SONDELBAY®, TERIPARATIDE BIOGARAN



Cartridges for reusable pens
MOVYMIA®, TERROSA®

- Risk factors for medication errors (MEs)**

National safety alert - 2021¹: dosing errors = injection of the entire solution (28 doses) as a single dose

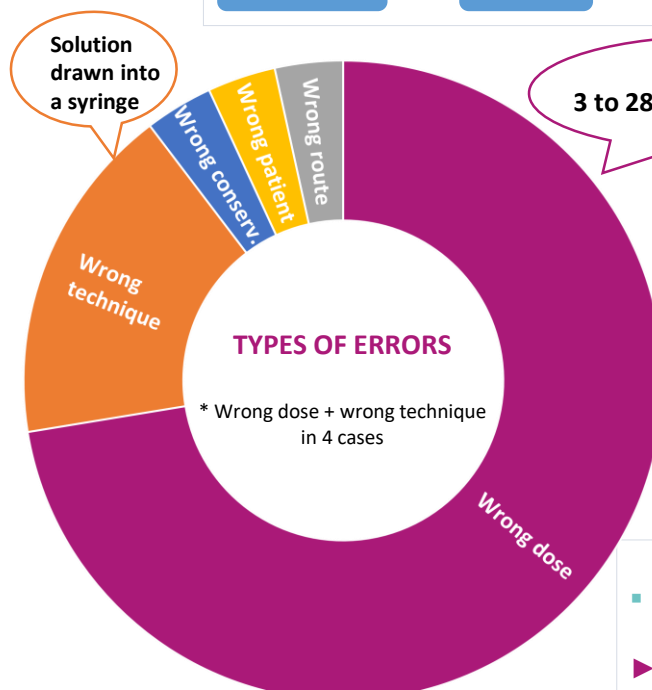
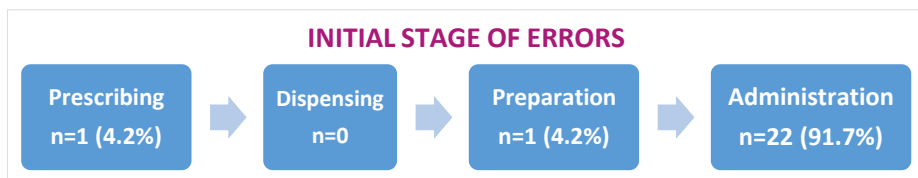
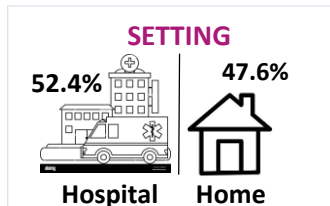
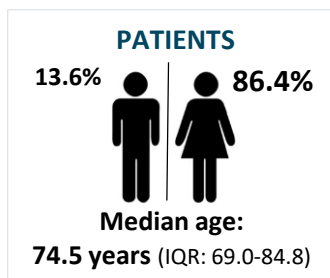
- Objective: to characterize MEs involving teriparatide formulations reported in the French Pharmacovigilance Database (FPVD)**

MATERIAL AND METHODS

Inclusion of **all MEs (risk, intercepted and actual MEs with or without adverse drug reaction (ADR)) involving teriparatide** (substance name) identified in the FPVD until December 2022.

RESULTS

- 24 MEs cases identified:** 24 actual MEs, including 4 cases occurred after the ANSM safety alert of 2021



Overdoses:
3 to 28-fold standard dose

ADR

- In 9 (42.9%) of the overdose cases
- Nature:** transient nausea/vomiting, fatigue, tachycardia/palpitations, headache, hypotension and/or hypercalcemia
- Management:** discontinuation of teriparatide, clinico-biological monitoring, hydration
- ▶ short hospitalization in 5 cases**

CAUSES OF ERRORS

- Human causes + causes related to product: in 13 reports**
- ▶ Improper packaging, pen without needle, difficulty of use: quality defect ?**

DISCUSSION - CONCLUSION

- MEs associated with multidose formulations of teriparatide **mainly consist of overdoses without serious clinical consequences but may require hospitalizations for surveillance** with costs to the health system.
- Risk minimization and prevention measures** (patients' education...) still need to be strengthened.

1. ANSM. 2021. <https://ansm.sante.fr/actualites/stylo-multidosesdans-le-traitement-de-losteoporose-ne-jamais-injecter-la-totalite-de-la-solution-enune-seule-fois>