Documents transmis le 27/04/2021 - Teriparatide

PUBLIÉ LE 21/05/2021 - MIS À JOUR LE 25/05/2021

- Teriparatide - Annexe 519 - List of Proposed (invented) names and Marketing Authorisation Holder in the Concerned Member States (219)
- Teriparatide - Letter of Access to ASMF for Teriparatide (eCTD-PTH) (2019)
- Teriparatide - Braille (2019)
- Teriparatide - Readability test (2006)
- Teriparatide - Proof of establisment (2018)
- Teriparatide - Submission of Application Dossier(s) for Marketing Authorisation (2019)
- Teriparatide - Champs de l'autorisation de fabrication (2006)
- Teriparatide - Letter of authorisation (2019)
- Teriparatide - Labelling (2019)
- Teriparatide - Information for generic, ‘hybrid’ or bio-similar applications (2018)
- Teriparatide - Qualified person's declaration concerning GMP compliance of the active substance manufacture "The QP declaration template"
- Teriparatide - Labelling (2013)
- Teriparatide - Non-GMO (genetically modified organisms)
- Teriparatide - Notice to applicants (2018)

Teriparatide - Package leaflet (2019)

Teriparatide - Summary of pharmacovigilance system (2013)

Teriparatide - Risk management plan (

Teriparatide - Summary of product characteristics (2019)

Teriparatide - Scientific advice given by member states (2015)

Teriparatide - History of e-CTD sequences (2019)

Teriparatide - Appendices (2019)

Teriparatide - Clinical overview (2018)

Teriparatide - Drug substance (2019)

Teriparatide - Drug product (2019)

Teriparatide - Introduction (2019)

Teriparatide - Nonclincal overview (2018)

Teriparatide - Regional information (2019)

Teriparatide - Concerned member state comments on day 180 assessment report to be sent at day 195 at the latest (2019)

Teriparatide - Concerned member state comments on day 120 assessment report to be sent at day 145 at the latest (2019)

Teriparatide - Concerned member state comments on day 70 assessment report to be sent at day 100 at the latest (2019)