MIS À JOUR LE 25/05/2021

Documents transmis le 16/03/2021 - Travoprost/Timolol

- AMM Travoprost/Timolol HOrus Pharma 40 microgrammes/ml + 5 mg/ml, collyre en solution (2018)
- Travoprost/Timolol - Annexe 53 - Extrait KBis Horus Pharma (2016)
- Travoprost/Timolol - Annexe 53 PH (2016)
- Travoprost/Timolol - Annexe 54 - Letter of authorization for communication on behalf of the Applicant/MAH (2016)
- Travoprost/Timolol - Annexe 56 (2017)
- Travoprost/Timolol - Annexe 56 - Certificate of GMP complicance of a manufacturer (2016)
- Travoprost/Timolol - Annexe 56 - Manufacturer's authorisation (2017)
- Travoprost/Timolol - Annexe 510 - Certificate of suitability (2016)
- Travoprost/Timolol - Annexe 511 - Letter of commitment (2016)
- Travoprost/Timolol - Annexe 511 (2016)
- Travoprost/Timolol - Annexe 517 (2016)
- Travoprost/Timolol - Annexe 519 - List of proposed (invented) names and marketing authorisation holders in the concerned member states for Travoprost-Timolol Horus Pharma (2016)
- Travoprost/Timolol - Braille (2016)
- Travoprost/Timolol - Bridging report (2018)

Travoprost/Timolol - Submission of data requested during the validation phase for Marketing Authorisation of Travoprost / Timolol 40 micrograms/ml + 5mg/ml preservative free eye drops, solution in multi dose container (2016)

Travoprost/Timolol - Submission of Application Dossier(s) for Marketing Authorisation of Travoprost / Timolol 40 micrograms/ml + 5mg/ml preservative free eye drops, solution in multi dose container (2016)

Travoprost/Timolol - Letter of access to DMF for Travoprost

Travoprost/Timolol - Justification for Absence of Environmental Risk Assessment (2016)

Travoprost/Timolol - Package leaflet: Information for the user (2016)

Travoprost/Timolol - Labelling (2016)

Travoprost/Timolol - Package leaflet: Information for the user (2016)

Travoprost/Timolol - Exploitant declaration for France (2016)

Travoprost/Timolol - Information for abridged application (2016)

Travoprost/Timolol - Notice to applicants (2015)

Travoprost/Timolol - Risk management plan (2016)

Travoprost/Timolol - Summary of pharmacovigilance system (2016)

Travoprost/Timolol - Summary of characteristics product (2016)

Travoprost/Timolol - Specimen (2016)

Travoprost/Timolol - History of e-CTD sequences (septembre 2016)

Travoprost/Timolol - History of e-CTD sequences (décembre 2016)

Travoprost/Timolol - Appendices (2016)

Travoprost/Timolol - Clinical overview (2016)

Travoprost/Timolol - Introduction (2016)

Travoprost/Timolol - Nonclinical summary (2016)

Travoprost/Timolol - Nonclinical overview (2016)

Travoprost/Timolol - Regional Information /For Eu (2016)

Travoprost/Timolol - Clinical Summary (2016)