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

PUBLIÉ LE 20/05/2021 - MIS À JOUR LE 25/05/2021

- AMM Travoprost/Timolol Chauvin 40 microgrammes/ml + 5 mg/ml, collyre en solution (2018)
- Travoprost/Timolol - Annexe 54 (2016)
- Travoprost/Timolol - Annexe 54 - Proc (2016)
- Travoprost/Timolol - Annexe 54 - Proc 2 (2016)
- Travoprost/Timolol - Annexe 510 (2016)
- Travoprost/Timolol - Annexe 511 (2016)
- Travoprost/Timolol - Annexe 511b (2016)
- Travoprost/Timolol - Annexe 517 (2016)
- Travoprost/Timolol - Annexe 519 (2016)
- Travoprost/Timolol - Manufacturer's authorisation (2016)
- Travoprost/Timolol - Avocat (2016)
- Travoprost/Timolol - Certificate of GMP compliance of a manufacturer (2016)
- Travoprost/Timolol - Braille (2018)
- 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 (2018)

Travoprost/Timolol - Letter of access to DMF (2016)

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

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

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 - Information for generic, “hybrid” or bio-similar applications (2016)

Travoprost/Timolol - Notice to applicants (2016)

Travoprost/Timolol - Notice to applicants 2B (2016)

Travoprost/Timolol - Risk management plan (2016)

Travoprost/Timolol - Summary of the Valeant group Pharmacovigilance System - Version 5 (2016)

Travoprost/Timolol - Summary of the Valeant group Pharmacovigilance System - Version 5 (2016)

Travoprost/Timolol - Summary of product characteristics (2016)

Travoprost/Timolol - Product information (2016)

Travoprost/Timolol - Extrait Kbis (2016)

Travoprost/Timolol - Registration (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 - Module 2.5 : Clinical overview (2016)

Travoprost/Timolol - Introduction (2016)

Travoprost/Timolol - Introduction b (2016)

Travoprost/Timolol - Module 2.4 : Non-clinical overview (2016)

Travoprost/Timolol - Module 2.4 : Non-clinical overview B (2016)

Travoprost/Timolol - Regional information / For EU

Travoprost/Timolol - Module 2.7 : Clinical summary (2016)