MIS À JOUR LE 25/05/2021

Documents transmis le 16/03/2021 - Travoprost

AMM Traglafka 40 microgrammes/ml, collyre en solution

Travoprost - Annexe 510 (2013)

Travoprost - Annexe 511 (2013)

Travoprost - Annexe 517 (2013)

Travoprost - Annexe 519 (2013)

Travoprost - Annexe 53 (2013)

Travoprost - Annexe 56 (2015)

Travoprost - Annexe 59 (2015)

Travoprost - Braille (2013)

Travoprost - Bridging report (2013)

Travoprost - Submission of a parallel Application Dossier(s) for Marketing Authorisation of Travoprost 40 micrograms/ml preservative free eye drops, solution in multi dose container with procedure number DK/H/2599/001/DC (2015)

Travoprost - History of e-CTD sequences (octobre 2015)

Travoprost - Declaration (2013)

Travoprost - Package leaflet: Information for the user (2013)

Travoprost - Justification for Absence of Environmental Risk Assessment (2013)

Travoprost - Labelling (2013)

Travoprost - Certificate of GMP compliance of a manufacturer (2013)

Travoprost - Certificate of GMP compliance of a manufacturer (2013)

Travoprost - Information for generic, “hybrid” or bio-similar applications (2013)

Travoprost - Notice to applicants (2013)

Travoprost - Letter of authorisation for employees (octobre 2015)

Travoprost - Risk management plan (2013)

Travoprost - Pharmacovigilance (2013)

Travoprost - Summary of product characteristics (2013)

Travoprost - Introduction (2013)

Travoprost - Appendices (2013)

Travoprost - Clinical summary (2013)

Travoprost - Quality overall summary (2013)

Travoprost - Regional information/for UE (2013)

Travoprost - Nonclinical summary (2013)

Travoprost - List of litterature references (modul 4)