

Documents transmis le 16/03/2021 -

Bimatropost/Timolol

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

AMM Bimatropost/Timolol Chauvin 0,3 mg/5 mg par ml, collyre en solution (2017)



Bimatropost/Timolol - Annexe 53 (2017)



Bimatropost/Timolol - Annexe 54 (2017)



Bimatropost/Timolol - Annexe 54 FR (2017)



Bimatropost/Timolol - Annexe 54 - Letter of authorisation for employees (2017)



Bimatropost/Timolol - Annexe 56 (2017)



Bimatropost/Timolol - Annexe 56 FR (2017)



Bimatropost/Timolol - Annexe 59 - Certificate of GMP compliance of a manufacturer (2017)



Bimatropost/Timolol - Annexe 510 - Letter of access (2017)



Bimatropost/Timolol - Annexe 517 (2017)



Bimatropost/Timolol - Annexe 519 - List of proposed (invented) names and marketing authorisation holders in the concerned member states (2017)



Bimatropost/Timolol - Manufacturer's authorisation (2017)



Bimatropost/Timolol - Braille (2017)



Bimatropost/Timolol - Submission of Application Dossier(s) for Marketing Authorisation of Vizibim Duo 0.3 mg/ml + 5 mg/ml, Preservative Free, eye drops solution, multidose container (2017)



Bimatropost/Timolol - Submission of Validation Responses sequence 0001 of Vizibim Duo 0.3 mg/ml + 5 mg/ml, Preservative Free, eye drops solution, multidose container (2017)



Bimatropost/Timolol - Certificate of suitability (2017)



Bimatropost/Timolol - Letter of commitment (2017)



Bimatropost/Timolol - Package leaflet: Information for the user (2017)



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



Bimatropost/Timolol - Justification for Absence of Environmental Risk Assessment (2017)



Bimatropost/Timolol - Labelling (2017)



Bimatropost/Timolol - Certificate of GMP compliance for a manufacturer (2017)



Bimatropost/Timolol - Information for abridged applications under Article 10(3) of Directive 2001/83/EC (2017)



Bimatropost/Timolol - Notice to applicants (2015)



Bimatropost/Timolol - Notice to applicants (2017)



Bimatropost/Timolol - Risk management plan (2016)



Bimatropost/Timolol - Risk management plan (2016)



Bimatropost/Timolol - Summary of the Valeant group Pharmacovigilance System (2016)



Bimatropost/Timolol - Summary of the Valeant group Pharmacovigilance System (2017)



Bimatropost/Timolol - Summary of product characteristics (2017)



Bimatropost/Timolol - Specimen (2017)



Bimatropost/Timolol - Track (2016)



Bimatropost/Timolol - Track (2016)



Bimatropost/Timolol - Appendices (2017)



Bimatropost/Timolol - Clinical overview (2017)



Bimatropost/Timolol - Clinical summary (2017)



Bimatropost/Timolol - Clinical overview (2017)



Bimatropost/Timolol - Nonclinical summary (2017)



Bimatropost/Timolol - Nonclinical overview (2017)



Bimatropost/Timolol - Introduction (2017)



Bimatropost/Timolol - Quality overall summary (2017)



Bimatropost/Timolol - Regional information / For EU (2017)

