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New Drug Application (NDA): 021262
Company: ALLERGAN

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Products on NDA 021262

CSVExcelPrint

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD
ALPHAGAN P	BRIMONIDINE TARTRATE	0.15%	SOLUTION/DROPS;OPHTHALMIC	Prescription	AT	Yes

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 021262

Original Approvals or Tentative Approvals

CSV

Excel

Print

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert
03/16/2001	ORIG-1	Approval	Type 3 - New Dosage Form	STANDARD	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2001/03162001.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2001/03162001.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/03162001.pdf)

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Supplements

CSV	Excel	Print				
Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert			
05/19/2014	SUPPL-24	Manufacturing (CMC)				
08/13/2010	SUPPL-20	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/02102010.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2010/02102010.pdf)			
05/22/2006	SUPPL-18	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/05222006.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2006/05222006.pdf)			
02/10/2004	SUPPL-13	Labeling	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2004/02102004.pdf)			
02/10/2004	SUPPL-10	Manufacturing (CMC)-Packaging	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2004/02102004.pdf)			

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
06/19/2002	SUPPL-8	Manufacturing (CMC)-Control	
04/12/2002	SUPPL-9	Manufacturing (CMC)	
01/22/2002	SUPPL-7	Manufacturing (CMC)	
12/20/2001	SUPPL-6	Efficacy-New Patient Population	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2001/0490S007_Brimonidine%20Tartrate%20Ophthalmic_Approv.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/0490S007_Brimonidine%20Tartrate%20Ophthalmic_Approv.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/0490S007_Brimonidine%20Tartrate%20Ophthalmic_Approv.pdf)
12/18/2001	SUPPL-4	Manufacturing (CMC)-Control	
12/04/2001	SUPPL-5	Manufacturing (CMC)	
10/23/2001	SUPPL-1	Manufacturing (CMC)	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
10/15/2001	SUPPL-3	Manufacturing (CMC)-Control	
06/05/2001	SUPPL-2	Manufacturing (CMC)	

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Labels for NDA 021262



Therapeutic Equivalents for NDA 021262

