

# Drugs@FDA: FDA-Approved Drugs

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New Drug Application (NDA): 021262

Company: ALLERGAN

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## Products on NDA 021262



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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

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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	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2001/03162001.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2001/03162001.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2001/03162001.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2001/03162001.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/rti/2001/03162001.pdf">Review (https://www.accessdata.fda.gov/drugsatfda_docs/rti/2001/03162001.pdf)</a>

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**Supplements**

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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	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/02102010.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/02102010.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2010/02102010.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2010/02102010.pdf)</a>
05/22/2006	SUPPL-18	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/05222006.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/05222006.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2006/05222006.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2006/05222006.pdf)</a>
02/10/2004	SUPPL-13	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2004/02102004.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2004/02102004.pdf)</a>
02/10/2004	SUPPL-10	Manufacturing (CMC)-Packaging	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2004/02102004.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2004/02102004.pdf)</a>

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) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2001/0490s007_brimonidine%20tartrate%20ophthalmic_approv.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2001/0490s007_brimonidine%20tartrate%20ophthalmic_approv.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/0490s007_brimonidine%20tartrate%20ophthalmic_approv.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/0490s007_brimonidine%20tartrate%20ophthalmic_approv.pdf</a> ) Review ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/0490s007_brimonidine%20tartrate%20ophthalmic_approv.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/0490s007_brimonidine%20tartrate%20ophthalmic_approv.pdf</a> )
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**

