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New Drug Application (NDA): 020490
Company: ALLERGAN

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Products on NDA 020490							▼
CSVExcelPrint							
Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	
ALPHAGAN	BRIMONIDINE TARTRATE	0.5%	SOLUTION/DROPS;OPHTHALMIC	Discontinued	None	No	
Showing 1 to 1 of 1 entries							

Approval Date(s) and History, Letters, Labels, Reviews for NDA 020490							▲
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	Notes
03/13/1997	ORIG-1	Approval	Type 3 - New Dosage Form	STANDARD		Label is not available on this site.

Showing 1 to 1 of 1 entries

Supplements

CSV	Excel	Print	
Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
03/23/2016	SUPPL-8	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020490s007_Brimonidine%20Tartrate%20Ophthalmic_Approv.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/020490s007_Alphagan.cfm)
12/20/2001	SUPPL-7	Efficacy-New Patient Population	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2001/020490s007_Brimonidine%20Tartrate%20Ophthalmic_Approv.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/020490s007_Alphagan.cfm) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/020490s007_Alphagan.cfm)
04/09/2001	SUPPL-6	Manufacturing (CMC)-Control	
05/26/2000	SUPPL-5	Manufacturing (CMC)-Control	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert
08/26/1999	SUPPL-4	Manufacturing (CMC)-Control	
05/20/1998	SUPPL-3	Manufacturing (CMC)	
02/25/1998	SUPPL-2	Manufacturing (CMC)-Control	
01/15/1998	SUPPL-1	Manufacturing (CMC)-Control	
Showing 1 to 8 of 8 entries			
Labels for NDA 020490			