# Drugs@FDA: FDA-Approved Drugs





**New Drug Application (NDA):** 020490
**Company:** ALLERGAN



## Products on NDA 020490

CSV | Excel | Print

| 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/2016/020 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/** |
| 12/20/2001 | SUPPL-7 | Efficacy-New Patient Population | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/lal Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nd 490S007_Brimonidine%20Tartrate%20Ophthalmic_Approv.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/20 490s007_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 | |

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**Labels for NDA 020490**