Drugs@FDA: FDA-Approved Drugs

New Drug Application (NDA): 017498
Company: PFIZER

EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=017498)

Products on NDA 017498

CSV | Excel | Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
MICRONASE	GLYBURIDE	1.25MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**	TABLET;ORAL	Discontinued	None	Yes	No
MICRONASE	GLYBURIDE	2.5MG	TABLET;ORAL	Discontinued	None	No	No
MICRONASE	GLYBURIDE	5MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**	TABLET;ORAL	Discontinued	None	Yes	No

Showing 1 to 3 of 3 entries

Approval Date(s) and History, Letters, Labels, Reviews for NDA 017498

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
05/01/1984	ORIG-1	Approval	Type 1 - New Molecular Entity	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	Note
05/22/2015	SUPPL-32	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/017498s032lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/017498Orig1s032ltr.pdf)	
10/15/2013	SUPPL-31	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/017498s031lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/017498Orig1s031ltr.pdf)	
02/01/2011	SUPPL-30	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/017498s030lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/017498s030ltr.pdf)	
08/27/2009	SUPPL-29	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/017498s029lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2009/017498s029ltr.pdf)	
10/27/2008	SUPPL-27	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/017498s027lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2008/017498s027ltr.pdf)	
11/30/1999	SUPPL-23	Manufacturing (CMC)		Label is not available on this site.

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
10/28/1999	SUPPL-21	Labeling		Label is not available on this site.
06/27/1997	SUPPL-20	Manufacturing (CMC)-Control		Label is not available on this site.
04/02/1997	SUPPL-19	Labeling		Label is not available on this site.
04/02/1997	SUPPL-18	Labeling		Label is not available on this site.
09/28/1995	SUPPL-16	Manufacturing (CMC)-Packaging		Label is not available on this site.
09/28/1995	SUPPL-15	Manufacturing (CMC)		Label is not available on this site.
01/21/1993	SUPPL-14	Labeling		Label is not available on this site.
07/27/1992	SUPPL-13	Labeling		Label is not available on this site.
11/15/1991	SUPPL-11	Manufacturing (CMC)-Control		Label is not available on this site.
12/14/1990	SUPPL-12	Labeling		Label is not available on this site.
04/27/1988	SUPPL-10	Manufacturing (CMC)		Label is not available on this site.
03/02/1988	SUPPL-8	Manufacturing (CMC)-Control		Label is not available on this site.
01/05/1988	SUPPL-9	Labeling		Label is not available on this site.
06/25/1987	SUPPL-7	Labeling		Label is not available on this site.
04/07/1987	SUPPL-6	Labeling		Label is not available on this site.
03/24/1986	SUPPL-5	Labeling		Label is not available on this site.
03/18/1986	SUPPL-4	Manufacturing (CMC)		Label is not available on this site.
07/24/1985	SUPPL-2	Manufacturing (CMC)-Control		Label is not available on this site.

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
01/15/1985	SUPPL-1	Manufacturing (CMC)-Control		Label is not available on this site.

Showing 1 to 25 of 25 entries

Labels for NDA 017498

Drugs@FDA: FDA-Approved Drugs

New Drug Application (NDA): 017498
Company: PFIZER

EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=017498)

Products on NDA 017498

Approval Date(s) and History, Letters, Labels, Reviews for NDA 017498

Labels for NDA 017498

CSV | Excel | Print

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
05/22/2015	SUPPL-32	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/017498s032lbl.pdf)**	
10/15/2013	SUPPL-31	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/017498s031lbl.pdf)**	
02/01/2011	SUPPL-30	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/017498s030lbl.pdf)**	
08/27/2009	SUPPL-29	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/017498s029lbl.pdf)**	
10/27/2008	SUPPL-27	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/017498s027lbl.pdf)**	

Showing 1 to 5 of 5 entries