

# Drugs@FDA: FDA-Approved Drugs

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New Drug Application (NDA): 020496  
Company: SANOFI AVENTIS US

[EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA:FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=020496\)](mailto:?SUBJECT=DRUGS@FDA:FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=020496)

## Products on NDA 020496

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
AMARYL	GLIMEPIRIDE	1MG	TABLET;ORAL	Prescription	AB	Yes	Yes
AMARYL	GLIMEPIRIDE	2MG	TABLET;ORAL	Prescription	AB	Yes	No
AMARYL	GLIMEPIRIDE	4MG	TABLET;ORAL	Prescription	AB	Yes	No

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## Approval Date(s) and History, Letters, Labels, Reviews for NDA 020496

### 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	Notes
11/30/1995	ORIG-1	Approval	Type 1 - New Molecular Entity	STANDARD	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/pre96/020496Orig1s000rev.pdf">Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/pre96/020496Orig1s000rev.pdf)</a>	Label is not available on this site.

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### Supplements

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
12/21/2018	SUPPL-29	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020496s029lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020496s029lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2018/020496Orig1s029ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2018/020496Orig1s029ltr.pdf)</a>	
12/19/2016	SUPPL-28	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020496s028lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020496s028lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/020496Orig1s028ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/020496Orig1s028ltr.pdf)</a>	
10/15/2013	SUPPL-27	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/020496s027lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/020496s027lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2013/020496Orig1s027ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2013/020496Orig1s027ltr.pdf)</a>	
08/01/2013	SUPPL-26	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/020496s026lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/020496s026lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2013/020496Orig1s026ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2013/020496Orig1s026ltr.pdf)</a>	
04/19/2013	SUPPL-25	Manufacturing (CMC)		Label is not available on this site.
03/14/2013	SUPPL-24	Manufacturing (CMC)		Label is not available on this site.

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
02/03/2012	SUPPL-22	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020496s022lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020496s022lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2012/020496s022ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2012/020496s022ltr.pdf</a> )	
06/04/2009	SUPPL-21	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020496s021lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020496s021lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/020496s021ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/020496s021ltr.pdf</a> )	
02/03/2009	SUPPL-19	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020496s018s019lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020496s018s019lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/020496s018_s019ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/020496s018_s019ltr.pdf</a> )	
02/03/2009	SUPPL-18	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020496s018s019lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020496s018s019lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/020496s018_s019ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/020496s018_s019ltr.pdf</a> )	
11/28/2005	SUPPL-15	Efficacy-New Patient Population	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020496s015lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020496s015lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2005/020496s015ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2005/020496s015ltr.pdf</a> )	
09/19/2005	SUPPL-16	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020496s016lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020496s016lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2005/020496s016ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2005/020496s016ltr.pdf</a> )	
08/16/2004	SUPPL-13	Labeling	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2004/20496s013ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2004/20496s013ltr.pdf</a> )	Label is not available on this site.
04/15/2002	SUPPL-7	Labeling	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2002/20496s7ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2002/20496s7ltr.pdf</a> )	Label is not available on this site.
07/21/2001	SUPPL-11	Manufacturing (CMC)		Label is not available on this site.
12/05/2000	SUPPL-10	Manufacturing (CMC)-Control		Label is not available on this site.
09/27/2000	SUPPL-5	Efficacy-Labeling Change With Clinical Data	Review (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20496-S005_Amaryl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20496-S005_Amaryl.pdf</a> )	Label is not available on this site.
08/29/2000	SUPPL-9	Manufacturing (CMC)-Control		Label is not available on this site.
01/06/2000	SUPPL-6	Manufacturing (CMC)		Label is not available on this site.
02/24/1999	SUPPL-2	Efficacy-New Indication	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/1999/20496s2ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/1999/20496s2ltr.pdf</a> ) Review ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/99/020496S002.cfm">https://www.accessdata.fda.gov/drugsatfda_docs/nda/99/020496S002.cfm</a> )	Label is not available on this site.
09/16/1998	SUPPL-4	Manufacturing (CMC)-Packaging		Label is not available on this site.
09/16/1998	SUPPL-3	Manufacturing (CMC)-Packaging		Label is not available on this site.
07/28/1997	SUPPL-1	Manufacturing (CMC)		Label is not available on this site.

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## Products on NDA 020496

## Approval Date(s) and History, Letters, Labels, Reviews for NDA 020496

## Labels for NDA 020496

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
12/21/2018	SUPPL-29	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020496s029lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020496s029lbl.pdf)</a>	
12/19/2016	SUPPL-28	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020496s028lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020496s028lbl.pdf)</a>	
10/15/2013	SUPPL-27	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/020496s027lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/020496s027lbl.pdf)</a>	
08/01/2013	SUPPL-26	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/020496s026lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/020496s026lbl.pdf)</a>	
02/03/2012	SUPPL-22	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020496s022lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020496s022lbl.pdf)</a>	
06/04/2009	SUPPL-21	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020496s021lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020496s021lbl.pdf)</a>	
02/03/2009	SUPPL-19	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020496s018s019lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020496s018s019lbl.pdf)</a>	
02/03/2009	SUPPL-18	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020496s018s019lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020496s018s019lbl.pdf)</a>	
11/28/2005	SUPPL-15	Efficacy-New Patient Population	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020496s015lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020496s015lbl.pdf)</a>	
09/19/2005	SUPPL-16	Labeling	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020496s016lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020496s016lbl.pdf)</a>	

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## Therapeutic Equivalents for NDA 020496

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[Labels for NDA 020496](#) ▼

[Therapeutic Equivalents for NDA 020496](#) ▲

**AMARYL**

**TABLET;ORAL; 1MG**  
**TE Code = AB**

[CSV](#) [Excel](#) [Print](#)

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application No.	Company
AMARYL	GLIMEPIRIDE	1MG	TABLET;ORAL	Prescription	Yes	AB	020496	SANOFI AVENTIS US
GLIMEPIRIDE	GLIMEPIRIDE	1MG	TABLET;ORAL	Prescription	No	AB	<a href="#">078181 (/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=078181)</a>	ACCORD HLTHCARE
GLIMEPIRIDE	GLIMEPIRIDE	1MG	TABLET;ORAL	Prescription	No	AB	<a href="#">202759 (/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=202759)</a>	AUROBINDO PHARMA LTD
GLIMEPIRIDE	GLIMEPIRIDE	1MG	TABLET;ORAL	Prescription	No	AB	<a href="#">077911 (/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=077911)</a>	CARLSBAD
GLIMEPIRIDE	GLIMEPIRIDE	1MG	TABLET;ORAL	Prescription	No	AB	<a href="#">077295 (/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=077295)</a>	CHARTWELL MOLECULAR
GLIMEPIRIDE	GLIMEPIRIDE	1MG	TABLET;ORAL	Prescription	No	AB	<a href="#">077091 (/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=077091)</a>	DR REDDYS LABS LTD
GLIMEPIRIDE	GLIMEPIRIDE	1MG	TABLET;ORAL	Prescription	No	AB	<a href="#">202112 (/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=202112)</a>	INDOCO REMEDIES
GLIMEPIRIDE	GLIMEPIRIDE	1MG	TABLET;ORAL	Prescription	No	AB	<a href="#">091220 (/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=091220)</a>	MICRO LABS
GLIMEPIRIDE	GLIMEPIRIDE	1MG	TABLET;ORAL	Prescription	No	AB	<a href="#">077370 (/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=077370)</a>	PRINSTON INC

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**TABLET;ORAL; 2MG**  
**TE Code = AB**

[CSV](#) [Excel](#) [Print](#)

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application No.	Company
AMARYL	GLIMEPIRIDE	2MG	TABLET;ORAL	Prescription	Yes	AB	020496	SANOFI AVENTIS US
GLIMEPIRIDE	GLIMEPIRIDE	2MG	TABLET;ORAL	Prescription	No	AB	<a href="#">078181 (/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=078181)</a>	ACCORD HLTHCARE
GLIMEPIRIDE	GLIMEPIRIDE	2MG	TABLET;ORAL	Prescription	No	AB	<a href="#">202759 (/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=202759)</a>	AUROBINDO PHARMA LTD
GLIMEPIRIDE	GLIMEPIRIDE	2MG	TABLET;ORAL	Prescription	No	AB	<a href="#">077911 (/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=077911)</a>	CARLSBAD

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application No.	Company
GLIMEPIRIDE	GLIMEPIRIDE	2MG	TABLET;ORAL	Prescription	No	AB	<a href="#">077295 (/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=077295)</a>	CHARTWELL MOLECULAR
GLIMEPIRIDE	GLIMEPIRIDE	2MG	TABLET;ORAL	Prescription	No	AB	<a href="#">077091 (/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=077091)</a>	DR REDDYS LABS LTD
GLIMEPIRIDE	GLIMEPIRIDE	2MG	TABLET;ORAL	Prescription	No	AB	<a href="#">202112 (/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=202112)</a>	INDOCO REMEDIES
GLIMEPIRIDE	GLIMEPIRIDE	2MG	TABLET;ORAL	Prescription	No	AB	<a href="#">091220 (/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=091220)</a>	MICRO LABS
GLIMEPIRIDE	GLIMEPIRIDE	2MG	TABLET;ORAL	Prescription	No	AB	<a href="#">077370 (/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=077370)</a>	PRINSTON INC

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**TABLET;ORAL; 4MG**  
TE Code = AB

CSV Excel Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application No.	Company
AMARYL	GLIMEPIRIDE	4MG	TABLET;ORAL	Prescription	Yes	AB	020496	SANOFI AVENTIS US
GLIMEPIRIDE	GLIMEPIRIDE	4MG	TABLET;ORAL	Prescription	No	AB	<a href="#">078181 (/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=078181)</a>	ACCORD HLTHCARE
GLIMEPIRIDE	GLIMEPIRIDE	4MG	TABLET;ORAL	Prescription	No	AB	<a href="#">202759 (/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=202759)</a>	AUROBINDO PHARMA LTD
GLIMEPIRIDE	GLIMEPIRIDE	4MG	TABLET;ORAL	Prescription	No	AB	<a href="#">077911 (/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=077911)</a>	CARLSBAD
GLIMEPIRIDE	GLIMEPIRIDE	4MG	TABLET;ORAL	Prescription	No	AB	<a href="#">077295 (/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=077295)</a>	CHARTWELL MOLECULAR
GLIMEPIRIDE	GLIMEPIRIDE	4MG	TABLET;ORAL	Prescription	No	AB	<a href="#">077091 (/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=077091)</a>	DR REDDYS LABS LTD
GLIMEPIRIDE	GLIMEPIRIDE	4MG	TABLET;ORAL	Prescription	No	AB	<a href="#">202112 (/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=202112)</a>	INDOCO REMEDIES
GLIMEPIRIDE	GLIMEPIRIDE	4MG	TABLET;ORAL	Prescription	No	AB	<a href="#">091220 (/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=091220)</a>	MICRO LABS
GLIMEPIRIDE	GLIMEPIRIDE	4MG	TABLET;ORAL	Prescription	No	AB	<a href="#">077370 (/scripts/cder/daf/index.cfm?event=overview.process&amp;AppNo=077370)</a>	PRINSTON INC

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