Label and Approval History

Drug Name(s)	**AMARYL**
FDA Application No.	**(NDA) 020496**
Active Ingredient(s)	**GLIMEPIRIDE**
Company	**SANOFI AVENTIS US**

Go to Approval History

Label Information

What information does a label include?[10]
Note: Not all labels are available in electronic format from FDA.

View the label approved on 10/15/2013 (PDF)[11] for NDA no. 020496

- **To see older, previously-approved labels, go to the "Approval History" section of this page. Older labels are for historical information only and should not be used for clinical purposes.**

Approval History
NDA 020496

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Approval dates can only be verified from 1984 to the present.

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Action Date	Supplement Number	Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
10/15/2013	027	Labeling Revision	Label (PDF)[12] Letter (PDF)[13]	
08/01/2013	026	Labeling Revision	Label (PDF)[14] Letter (PDF)[15]	
04/19/2013	025	Manufacturing Change or Addition		This supplement type does not usually require new labeling.
03/14/2013	024	Manufacturing Change or Addition		This supplement type does not usually require new labeling.
02/03/2012	022	Labeling Revision	Label (PDF)[16] Letter (PDF)[17]	
06/04/2009	021	Labeling Revision	Label (PDF)[18] Letter (PDF)[19]	
02/03/2009	019	Labeling Revision	Label (PDF)[20] Letter (PDF)[21]	
02/03/2009	018	Labeling Revision	Label (PDF)[22] Letter (PDF)[23]	
11/28/2005	015	Patient Population Altered	Label (PDF)[24] Letter (PDF)[25]	
09/19/2005	016	Labeling Revision	Label (PDF)[26] Letter (PDF)[27]	
08/16/2004	013	Labeling Revision	Letter (PDF)[28]	Label is not available

			on this site.
07/21/2001 011	Manufacturing Change or Addition		This supplement type does not usually require new labeling.
12/05/2000 010	Control Supplement		This supplement type does not usually require new labeling.
09/27/2000 005	Efficacy Supplement with Clinical Data to Support	Review (PDF)[30]	Label is not available on this site.
08/29/2000 009	Control Supplement		This supplement type does not usually require new labeling.
01/06/2000 006	Manufacturing Change or Addition		This supplement type does not usually require new labeling.
02/24/1999 002	New or Modified Indication	Letter (PDF)[31] Review [32]	Label is not available on this site.
09/16/1998 004	Package Change		Label is not available on this site.
09/16/1998 003	Package Change		Label is not available on this site.
07/28/1997 001	Manufacturing Change or Addition		This supplement type does not usually require new labeling.
11/30/1995 000	Approval		Label is not available on this site.

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