

# Drugs@FDA: FDA-Approved Drugs

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New Drug Application (NDA): 020357  
Company: EMD SERONO INC

EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=020357)

## Products on NDA 020357

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
GLUCOPHAGE	METFORMIN HYDROCHLORIDE	500MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**	TABLET;ORAL	Discontinued	None	Yes	No
GLUCOPHAGE	METFORMIN HYDROCHLORIDE	850MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**	TABLET;ORAL	Discontinued	None	Yes	No
GLUCOPHAGE	METFORMIN HYDROCHLORIDE	625MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**	TABLET;ORAL	Discontinued	None	Yes	No
GLUCOPHAGE	METFORMIN HYDROCHLORIDE	750MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**	TABLET;ORAL	Discontinued	None	Yes	No
GLUCOPHAGE	METFORMIN HYDROCHLORIDE	1GM **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**	TABLET;ORAL	Discontinued	None	Yes	No

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## Approval Date(s) and History, Letters, Labels, Reviews for NDA 020357

### 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
03/03/1995	ORIG-1	Approval	Type 1 - New Molecular Entity	PRIORITY	Review (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/pre96/020357Orig1s000rev.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/pre96/020357Orig1s000rev.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
05/30/2018	SUPPL-34	Labeling-Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020357s034,021202s018lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020357s034,021202s018lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2018/020357Orig1s034, 021202Orig1s018ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2018/020357Orig1s034, 021202Orig1s018ltr.pdf</a> )	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
04/05/2017	SUPPL-39	Labeling-Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020357s037s039,021202s021s023lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020357s037s039,021202s021s023lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/020357Orig1s037s039,021202Orig1s021s023ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/020357Orig1s037s039,021202Orig1s021s023ltr.pdf</a> )	
04/05/2017	SUPPL-37	Labeling-Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020357s037s039,021202s021s023lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020357s037s039,021202s021s023lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/020357Orig1s037s039,021202Orig1s021s023ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/020357Orig1s037s039,021202Orig1s021s023ltr.pdf</a> )	
11/13/2013	SUPPL-36	Manufacturing (CMC)		Label is not available on this site.
03/14/2013	SUPPL-35	Manufacturing (CMC)		Label is not available on this site.
08/27/2008	SUPPL-31	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/020357s031,021202s016lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/020357s031,021202s016lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2008/020357s031,021202s016ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2008/020357s031,021202s016ltr.pdf</a> )	
11/01/2006	SUPPL-30	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/020357s030,021202s015lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/020357s030,021202s015lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2006/020357s030,021202s015ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2006/020357s030,021202s015ltr.pdf</a> )	
03/19/2004	SUPPL-27	Labeling	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2004/20357slr026,027,21202slr011,013ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2004/20357slr026,027,21202slr011,013ltr.pdf</a> )	Label is not available on this site.
03/19/2004	SUPPL-26	Labeling	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2004/20357slr026,027,21202slr011,013ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2004/20357slr026,027,21202slr011,013ltr.pdf</a> )	Label is not available on this site.
01/08/2002	SUPPL-24	Labeling	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2002/21202s3ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2002/21202s3ltr.pdf</a> )	Label is not available on this site.
04/19/2001	SUPPL-20	Efficacy-Labeling Change With Clinical Data	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2001/20357S20ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2001/20357S20ltr.pdf</a> ) Review (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/020357_S020_GLUCOPHAGE_AP.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/020357_S020_GLUCOPHAGE_AP.pdf</a> )	Label is not available on this site.
02/08/2001	SUPPL-22	Labeling		Label is not available on this site.
12/15/2000	SUPPL-19	Efficacy-New Patient Population	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20357S019_Glucophage_prntlbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20357S019_Glucophage_prntlbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2000/20357S19LTR.PDF">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2000/20357S19LTR.PDF</a> ) Review ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20357s19_glucopehage.cfm">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20357s19_glucopehage.cfm</a> )	
08/04/2000	SUPPL-21	Manufacturing (CMC)		Label is not available on this site.
09/22/1999	SUPPL-17	Efficacy-Labeling Change With Clinical Data	Review (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/99/20357S17.PDF">https://www.accessdata.fda.gov/drugsatfda_docs/nda/99/20357S17.PDF</a> )	Label is not available on this site.
06/07/1999	SUPPL-18	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
06/01/1999	SUPPL-15	Manufacturing (CMC)		Label is not available on this site.
03/12/1999	SUPPL-16	Manufacturing (CMC)		Label is not available on this site.
12/04/1998	SUPPL-14	Manufacturing (CMC)-Control		Label is not available on this site.
11/18/1998	SUPPL-13	Manufacturing (CMC)		Label is not available on this site.
11/05/1998	SUPPL-11	Manufacturing (CMC)-Formulation		Label is not available on this site.
10/22/1998	SUPPL-10	Efficacy-New Indication	<b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20357s10ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20357s10ltr.pdf</a> ) <b>Review (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/020357s010.cfm">https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/020357s010.cfm</a> )	Label is not available on this site.
07/02/1998	SUPPL-9	Manufacturing (CMC)		Label is not available on this site.
05/15/1998	SUPPL-7	Manufacturing (CMC)		Label is not available on this site.
02/10/1998	SUPPL-8	Labeling		Label is not available on this site.
11/06/1997	SUPPL-6	Labeling	<b>Review (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/97/020357a_s006.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/97/020357a_s006.pdf</a> )	Label is not available on this site.
06/06/1997	SUPPL-5	Manufacturing (CMC)		Label is not available on this site.
07/26/1996	SUPPL-4	Manufacturing (CMC)		Label is not available on this site.

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
04/30/1996	SUPPL-3	Manufacturing (CMC)-Control		Label is not available on this site.
09/13/1995	SUPPL-2	Manufacturing (CMC)-Packaging		Label is not available on this site.

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Labels for NDA 020357



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EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=020357)

Products on NDA 020357

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05/30/2018	SUPPL-34	Labeling-Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020357s034,021202s018lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020357s034,021202s018lbl.pdf</a> )	
04/05/2017	SUPPL-39	Labeling-Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020357s037s039,021202s021s023lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020357s037s039,021202s021s023lbl.pdf</a> )	
04/05/2017	SUPPL-37	Labeling-Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020357s037s039,021202s021s023lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020357s037s039,021202s021s023lbl.pdf</a> )	
08/27/2008	SUPPL-31	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/020357s031,021202s016lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/020357s031,021202s016lbl.pdf</a> )	
11/01/2006	SUPPL-30	Labeling	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/020357s030,021202s015lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/020357s030,021202s015lbl.pdf</a> )	
12/15/2000	SUPPL-19	Efficacy-New Patient Population	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20357S019_Glucoophage_prntlbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20357S019_Glucoophage_prntlbl.pdf</a> )	

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