

# Drugs@FDA: FDA-Approved Drugs

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New Drug Application (NDA): 202270

Company: MSD SUB MERCK

EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=202270)

- [Medication Guide \(https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/202270s026lbl.pdf#page=34\)](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/202270s026lbl.pdf#page=34)
- [Summary Review \(http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2012/202270Orig1s000SumR.pdf\)](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202270Orig1s000SumR.pdf)

## Products on NDA 202270

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
JANUMET XR	METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE	500MG;EQ 50MG BASE	TABLET, EXTENDED RELEASE;ORAL	Prescription	None	Yes	No
JANUMET XR	METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE	1GM;EQ 50MG BASE	TABLET, EXTENDED RELEASE;ORAL	Prescription	None	Yes	No
JANUMET XR	METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE	1GM;EQ 100MG BASE	TABLET, EXTENDED RELEASE;ORAL	Prescription	None	Yes	Yes

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## Approval Date(s) and History, Letters, Labels, Reviews for NDA 202270

### 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
02/02/2012	ORIG-1	Approval	Type 3 - New Dosage Form	STANDARD	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202270s000lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202270s000lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/202270s000ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/202270s000ltr.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202270_janumet_xr_toc.cfm">Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202270_janumet_xr_toc.cfm)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202270Orig1s000SumR.pdf">Summary Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202270Orig1s000SumR.pdf)</a>	

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### Supplements

CSV Excel Print

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
06/21/2022	SUPPL-26	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/202270s026lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/202270s026lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/021995Orig1s050, 022044Orig1s052, 202270Orig1s026ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/021995Orig1s050, 022044Orig1s052, 202270Orig1s026ltr.pdf)</a>	
11/04/2021	SUPPL-25	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/202270s025lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/202270s025lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/202270Orig1s025ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/202270Orig1s025ltr.pdf)</a>	
12/04/2020	SUPPL-22	Efficacy-Labeling Change With Clinical Data	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/202270Orig1s022lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/202270Orig1s022lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/021995Orig1s047, 022044Orig1s048, 202270Orig1s022ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/021995Orig1s047, 022044Orig1s048, 202270Orig1s022ltr.pdf)</a>	
08/12/2019	SUPPL-19	Efficacy-Labeling Change With Clinical Data	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/202270s019lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/202270s019lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/021995Orig1s045, 202270Orig1s019, 022044Orig1s046.ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/021995Orig1s045, 202270Orig1s019, 022044Orig1s046.ltr.pdf)</a>	
07/01/2019	SUPPL-20	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/202270s020lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/202270s020lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/021995Orig1s046, 022044Orig1s047, 202270Orig1s020ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/021995Orig1s046, 022044Orig1s047, 202270Orig1s020ltr.pdf)</a>	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
02/09/2018	SUPPL-18	Labeling-Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/202270s018lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/202270s018lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/021995Orig1s042,022044s043,202270Orig1s018ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/021995Orig1s042,022044s043,202270Orig1s018ltr.pdf</a> )	
08/10/2017	SUPPL-17	Labeling-Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/202270s017lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/202270s017lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/021995Orig1s040,022044Orig1s042,202270Orig1s017ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/021995Orig1s040,022044Orig1s042,202270Orig1s017ltr.pdf</a> )	
01/18/2017	SUPPL-16	Labeling-Package Insert, Labeling-Medication Guide	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/202270s015s016lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/202270s015s016lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/202270Orig1s015,s016ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/202270Orig1s015,s016ltr.pdf</a> )	
01/18/2017	SUPPL-15	Labeling-Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/202270s015s016lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/202270s015s016lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/202270Orig1s015,s016ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/202270Orig1s015,s016ltr.pdf</a> )	
08/28/2015	SUPPL-10	Labeling-Medication Guide	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/202270s010lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/202270s010lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/021995Orig1s034,022044Orig1s035,202270Orig1s010ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/021995Orig1s034,022044Orig1s035,202270Orig1s010ltr.pdf</a> )	
04/27/2015	SUPPL-9	Labeling-Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/202270s009lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/202270s009lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/021995Orig1s033,022044Orig1s034,202270Orig1s009ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/021995Orig1s033,022044Orig1s034,202270Orig1s009ltr.pdf</a> )	
09/19/2014	SUPPL-8	Manufacturing (CMC)		Label is not available on this site.
02/12/2014	SUPPL-6	Labeling-Medication Guide	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/202270s006lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/202270s006lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/202270Orig1s006ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/202270Orig1s006ltr.pdf</a> )	
10/17/2013	SUPPL-5	Manufacturing (CMC)		Label is not available on this site.
07/19/2013	SUPPL-4	Manufacturing (CMC)		Label is not available on this site.
04/10/2013	SUPPL-1	Manufacturing (CMC)		Label is not available on this site.
02/11/2013	SUPPL-3	Labeling-Container/Carton Labels, Labeling-Medication Guide	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/202270s003lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/202270s003lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/202270Orig1s003ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/202270Orig1s003ltr.pdf</a> )	
10/18/2012	SUPPL-2	Labeling-Medication Guide	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202270s002lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202270s002lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/202270Orig1s002ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/202270Orig1s002ltr.pdf</a> )	

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- [Medication Guide \(https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/202270s026lbl.pdf#page=34\)](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/202270s026lbl.pdf#page=34)
- [Summary Review \(http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2012/202270Orig1s000SumR.pdf\)](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202270Orig1s000SumR.pdf)

**Products on NDA 202270** ▼

**Approval Date(s) and History, Letters, Labels, Reviews for NDA 202270** ▼

**Labels for NDA 202270** ▲

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
06/21/2022	SUPPL-26	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/202270s026lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/202270s026lbl.pdf)</a>	
11/04/2021	SUPPL-25	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/202270s025lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/202270s025lbl.pdf)</a>	
12/04/2020	SUPPL-22	Efficacy-Labeling Change With Clinical Data	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/202270Orig1s022lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/202270Orig1s022lbl.pdf)</a>	
08/12/2019	SUPPL-19	Efficacy-Labeling Change With Clinical Data	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/202270s019lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/202270s019lbl.pdf)</a>	
07/01/2019	SUPPL-20	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/202270s020lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/202270s020lbl.pdf)</a>	
02/09/2018	SUPPL-18	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/202270s018lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/202270s018lbl.pdf)</a>	
08/10/2017	SUPPL-17	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/202270s017lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/202270s017lbl.pdf)</a>	
01/18/2017	SUPPL-16	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/202270s015s016lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/202270s015s016lbl.pdf)</a>	
01/18/2017	SUPPL-16	Labeling-Medication Guide	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/202270s015s016lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/202270s015s016lbl.pdf)</a>	
01/18/2017	SUPPL-15	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/202270s015s016lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/202270s015s016lbl.pdf)</a>	
08/28/2015	SUPPL-10	Labeling-Medication Guide	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/202270s010lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/202270s010lbl.pdf)</a>	
04/27/2015	SUPPL-9	Labeling-Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/202270s009lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/202270s009lbl.pdf)</a>	
02/12/2014	SUPPL-6	Labeling-Medication Guide	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/202270s006lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/202270s006lbl.pdf)</a>	
02/11/2013	SUPPL-3	Labeling-Container/ Carton Labels	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/202270s003lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/202270s003lbl.pdf)</a>	
02/11/2013	SUPPL-3	Labeling-Medication Guide	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/202270s003lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/202270s003lbl.pdf)</a>	

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10/18/2012	SUPPL-2	Labeling-Medication Guide	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202270s002lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202270s002lbl.pdf</a> )	
02/02/2012	ORIG-1	Approval	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202270s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202270s000lbl.pdf</a> )	

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