

# Drugs@FDA: FDA Approved Drug Products

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New Drug Application (NDA): 050577

Company: TEVA PHARMS USA

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## Products on NDA 050577



### CSVExcelPrint

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
ZANOSAR	STREPTOZOCIN	1GM/VIAL	INJECTABLE;INJECTION	Prescription	Yes	None

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## Approval Date(s) and History, Letters, Labels, Reviews for NDA 050577



Original Approvals or Tentative Approvals

### CSVExcelPrint

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes
05/07/1982	ORIG-1	Approval	Type 1 - New Molecular Entity	STANDARD		Label is not available on this site.

Showing 1 to 1 of 1 entries

## Supplements

### CSVExcelPrint

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
11/14/2016	SUPPL-42	MANUF (CMC)	
01/05/2015	SUPPL-41	Manufacturing (CMC)	
01/05/2015	SUPPL-40	Manufacturing (CMC)	
09/23/2014	SUPPL-39	Manufacturing (CMC)	
07/31/2014	SUPPL-38	Manufacturing (CMC)	

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
08/09/2013	SUPPL-36	Manufacturing (CMC)	
12/12/2012	SUPPL-37	Manufacturing (CMC)	
12/04/2012	SUPPL-35	Manufacturing (CMC)	
12/04/2012	SUPPL-34	Manufacturing (CMC)	
12/04/2012	SUPPL-20	Manufacturing (CMC)	
01/22/2003	SUPPL-16	Labeling	<b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2003/50577">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2003/50577</a> )
12/30/2002	SUPPL-14	Labeling	<b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2002/50577">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2002/50577</a> )
10/22/2002	SUPPL-17	Manufacturing (CMC)-Control	

<b>Action Date</b>	<b>Submission</b>	<b>Submission Classification</b>	<b>Letters, Reviews, Labels, Patient Package Insert</b>
04/03/2000	SUPPL-15	Manufacturing (CMC)-Control	
05/05/1999	SUPPL-13	Labeling	
06/29/1995	SUPPL-12	Manufacturing (CMC)-Control	
09/27/1994	SUPPL-11	Manufacturing (CMC)	
08/11/1994	SUPPL-7	Manufacturing (CMC)-Control	
06/14/1993	SUPPL-10	Manufacturing (CMC)-Control	
04/22/1988	SUPPL-6	Labeling	
11/17/1986	SUPPL-5	Labeling	

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