

# Drugs@FDA: FDA Approved Drug Products

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New Drug Application (NDA) 022527  
Company NOVARTIS

- [Medication Guide \(https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2019/022527s261bl.pdf#page=26\)](https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/022527s261bl.pdf#page=26)
- [Other Important Information from FDA \(http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm284282.htm\)](http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm284282.htm)
- [Summary Review \(http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2010/022527Orig1s000sumr.pdf\)](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022527Orig1s000sumr.pdf)

### Products on NDA 022527

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code
GILENYA	FINGOLIMOD HYDROCHLORIDE	EQ 0.5MG BASE	CAPSULE;ORAL	Prescription	None
GILENYA	FINGOLIMOD HYDROCHLORIDE	EQ 0.25MG BASE	CAPSULE;ORAL	Prescription	None

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### [Approval Date\(s\) and History, Letters, Labels, Reviews for NDA 022527](#)

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