

VORICONAZOLE - voriconazole injection, powder, lyophilized, for solution
Zydus Lifesciences Limited

VORICONAZOLE FOR INJECTION

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - Container Label

NDC 70771-1413-1

Voriconazole

for Injection

200 mg per vial

Sterile Single-Dose Vial

For Intravenous Infusion Only

Rx Only

(01)00370771141319

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

DOSAGE AND USE:
Reconstitute with 19 mL of Water for Injection to give a clear solution containing 10 mg/mL Voriconazole and an extractable volume of 20 mL.
Must be further diluted before use. For appropriate diluents and storage recommendations, refer to prescribing information.
Discard unused portion.

FOR INTRAVENOUS ADMINISTRATION
* With reconstitution each mL contains 10 mg Voriconazole, USP and 160 mg Betadex Sulfobutyl Ether Sodium, NF

NDC 70771-1413-1

Voriconazole
for Injection

200 mg* per Vial

Sterile Single-Dose Vial
For Intravenous Infusion Only

zydus
pharmaceuticals

Rx only

No Preservatives
This container closure is not made with natural rubber latex.
Code No.: GUJ/DRUG/1081
Manufactured by:
Cadila Healthcare Limited
Ahmedabad, India

Rev: 07/18
XXXXXX

Lot:
Exp:

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - Carton Label

NDC 70771-1413-1

Voriconazole

for Injection

200 mg per vial

Sterile Single-Dose Vial

For Intravenous Infusion Only

1 Vial

Rx Only



VORICONAZOLE

voriconazole injection, powder, lyophilized, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1413
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VORICONAZOLE (UNII: JFU09I87TR) (VORICONAZOLE - UNII:JFU09I87TR)	VORICONAZOLE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SULFOBUTYLETHER .BETA.-CYCLODEXTRIN (UNII: 2PP9364507)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1413-1	1 in 1 CARTON	01/03/2019	
1		20 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208983	01/03/2019	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1413) , MANUFACTURE(70771-1413)

Revised: 11/2022

Zydus Lifesciences Limited