

**MYCOPHENOLATE MOFETIL- mycophenolate mofetil injection, powder, lyophilized, for solution**  
**Zydus Lifesciences Limited**

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**MYCOPHENOLATE MOFETIL FOR INJECTION, USP**

**SPL MEDGUIDE**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

PRINCIPAL DISPLAY PANEL - MYCOPHENOLATE MOFETIL 500 MG CONTAINER LABEL

NDC 70771-1084-1

Mycophenolate Mofetil for Injection, USP

(500 mg per Vial)

FOR INTRAVENOUS INFUSION ONLY

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

SINGLE DOSE VIAL

Rx only

Zydus Pharmaceuticals

NDC 70771-1084-1

**Mycophenolate Mofetil**  
for Injection, USP

**500 mg per Vial**

FOR INTRAVENOUS INFUSION ONLY

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

**zydus** pharmaceuticals

SINGLE DOSE VIAL  
Rx only

Rev.: 09/17

Lot: \_\_\_\_\_  
Exp: \_\_\_\_\_

(01)00370771108411

Each vial contains the equivalent of 500 mg mycophenolate mofetil, USP (as the hydrochloride salt), 25 mg polysorbate 80, and 5 mg citric acid.  
**Usual Dosage:** See package insert for complete prescribing information.  
Store powder at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]; excursions permitted to 15° to 30°C (59° to 86°F).  
**KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**  
This container closure is not made with natural rubber latex.  
Code No.: GUJ/DRUG/1081  
**Manufactured by:**  
Cadila Healthcare Ltd.  
Ahmedabad, India

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PRINCIPAL DISPLAY PANEL - MYCOPHENOLATE MOFETIL 500 MG CARTON LABEL

NDC 70771-1084-8

Mycophenolate Mofetil for Injection, USP

(500 mg per Vial)

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

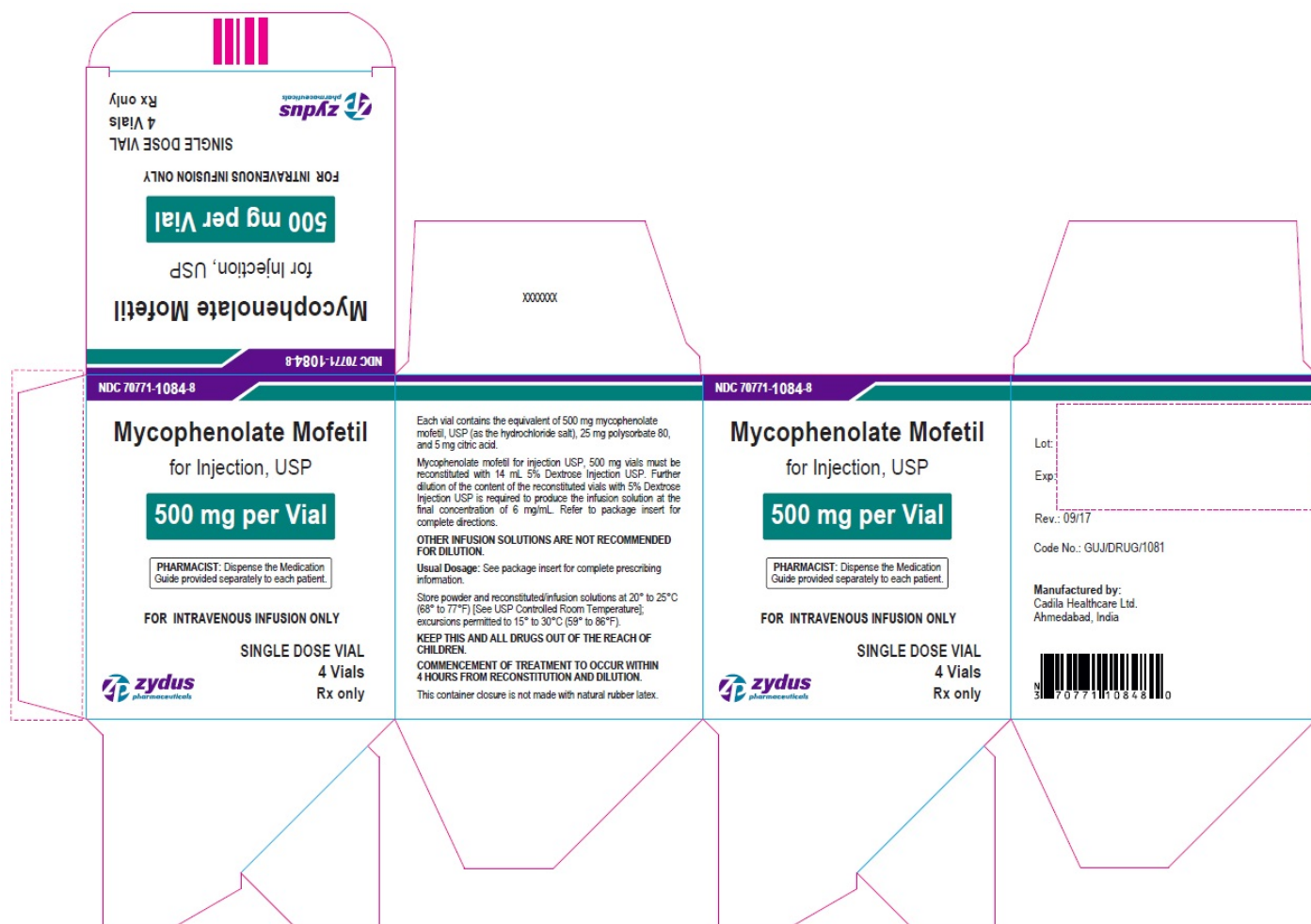
FOR INTRAVENOUS INFUSION ONLY

SINGLE DOSE VIAL

4 Vials

Rx only

Zydus Pharmaceuticals



## MYCOPHENOLATE MOFETIL

mycophenolate mofetil injection, powder, lyophilized, for solution

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1084
<b>Route of Administration</b>	INTRAVENOUS		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MYCOPHENOLATE MOFETIL (UNII: 9242ECW6R0) (MYCOPHENOLIC ACID -	MYCOPHENOLATE	500 mg

UNII:HU9DX48N0T)		MOFETIL	in 20 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
WATER (UNII: 059QF0KO0R)				
HYDROCHLORIC ACID (UNII: QTT17582CB)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:70771-1084-8	4 in 1 CARTON	09/22/2017	
1		20 mL in 1 VIAL; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA204473		09/22/2017	

**Labeler** - Zydus Lifesciences Limited (918596198)

**Registrant** - Zydus Lifesciences Limited (918596198)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1084) , MANUFACTURE(70771-1084)

Revised: 10/2023

Zydus Lifesciences Limited