

**LEVOFLOXACIN- levofloxacin injection, solution**  
**Zydus Lifesciences Limited**

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**LEVOFLOXACIN INJECTION**

**SPL MEDGUIDE**

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 500 MG/20 ML CONTAINER LABEL**

**NDC 70771-1079-2**

**Levofloxacin**

**Injection**

**500 mg/20 mL**

**(25 mg/mL)**

**For Intravenous Infusion**

**Attention Pharmacist: Dispense the accompanying Medication Guide to each patient.**

**20 mL Single-Dose Vial**

**Rx only**

**zydus pharmaceuticals**

**NDC 70771-1079-2**

**Levofloxacin Injection**

**500 mg/20 mL (25 mg/mL)**

**For Intravenous Infusion**

**Attention Pharmacist: Dispense the accompanying Medication Guide to each Patient.**

**20 mL Single-Dose Vial**

**Rx only**

**zydus pharmaceuticals**

Directions for Use: Single-Dose Vial. Not for direct infusion. Vial contents must be further diluted with an appropriate solution prior to intravenous administration. See insert for the preparation of intravenous solutions, stability, storage, compatability, and usual adult dosage.

Each vial contains a concentrated solution in Water for Injection, USP with the equivalent of 500 mg of levofloxacin, USP. May contain diluted Hydrochloric Acid, NF and/or Sodium Hydroxide, NF for pH adjustment. pH range 3.8 to 5.8.

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

Code No.: GUJ/DRUG/1081

Manufactured by: Cadila Healthcare Limited Ahmedabad, India

Rev : 06/17  
XXXXXX

Lot:

Exp:

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 500 MG/20 ML CARTON LABEL**

**NDC 70771-1079-2**

**Levofloxacin**

**Injection**

**500 mg/20 mL**

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**(25 mg/mL)**

**For Intravenous Infusion**

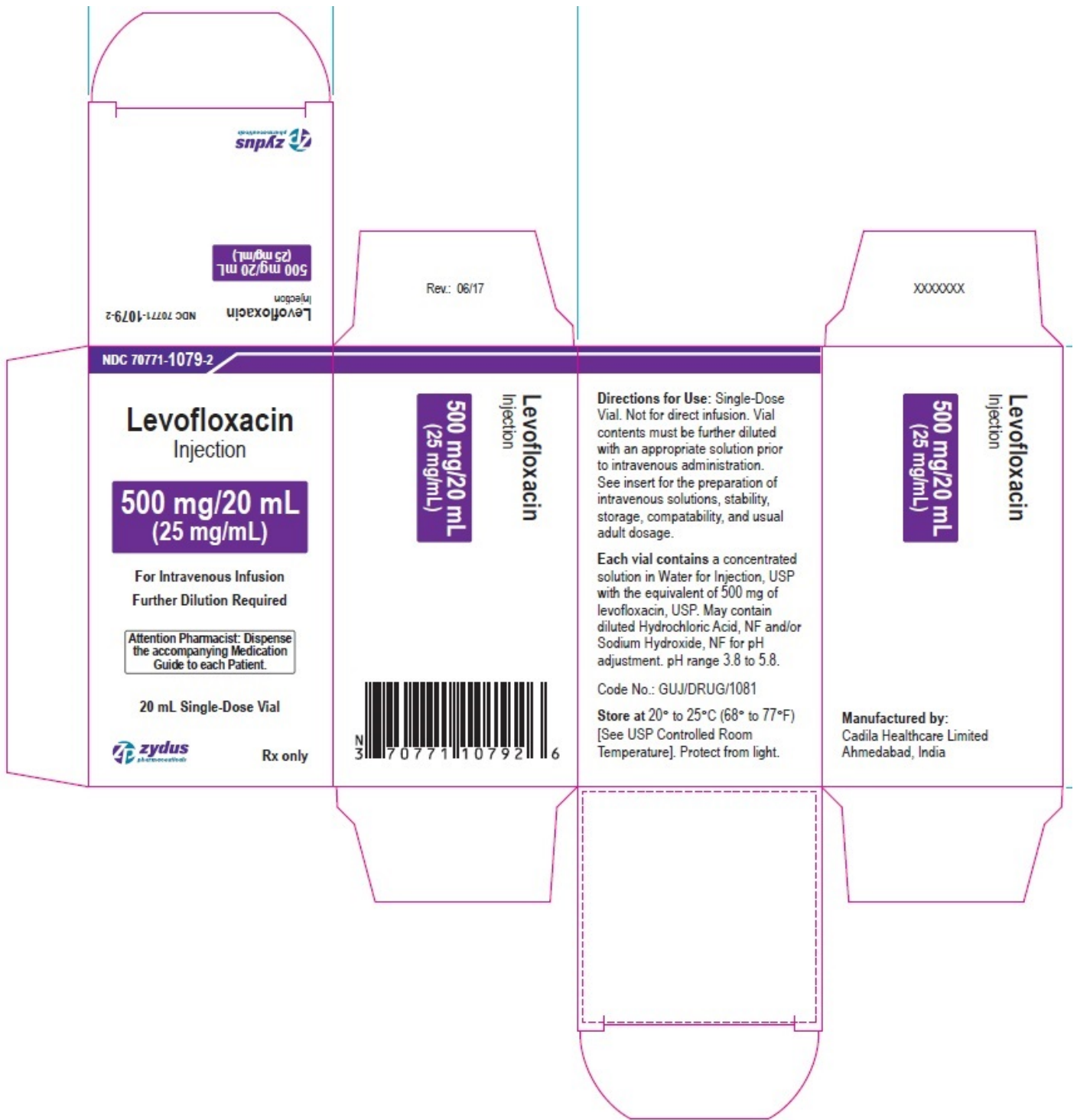
**Further Dilution Required**

**Attention Pharmacist: Dispense the accompanying Medication Guide to each patient.**

**20 mL Single-Dose Vial**

**Rx only**

**zydus pharmaceuticals**



**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 750 MG/30 ML CONTAINER LABEL**

**NDC 70771-1079-3**

**Levofloxacin**

**Injection**

**750 mg/30 mL**

**(25 mg/mL)**

**For Intravenous Infusion**

**Attention Pharmacist: Dispense the accompanying Medication Guide to each patient.**

**30 mL Single-Dose Vial**

**Rx only**

**zydus pharmaceuticals**

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 750 MG/30 ML CARTON LABEL**

**NDC 70771-1079-3**

**Levofloxacin**

**Injection**

**750 mg/30 mL**

**(25 mg/mL)**

**For Intravenous Infusion**

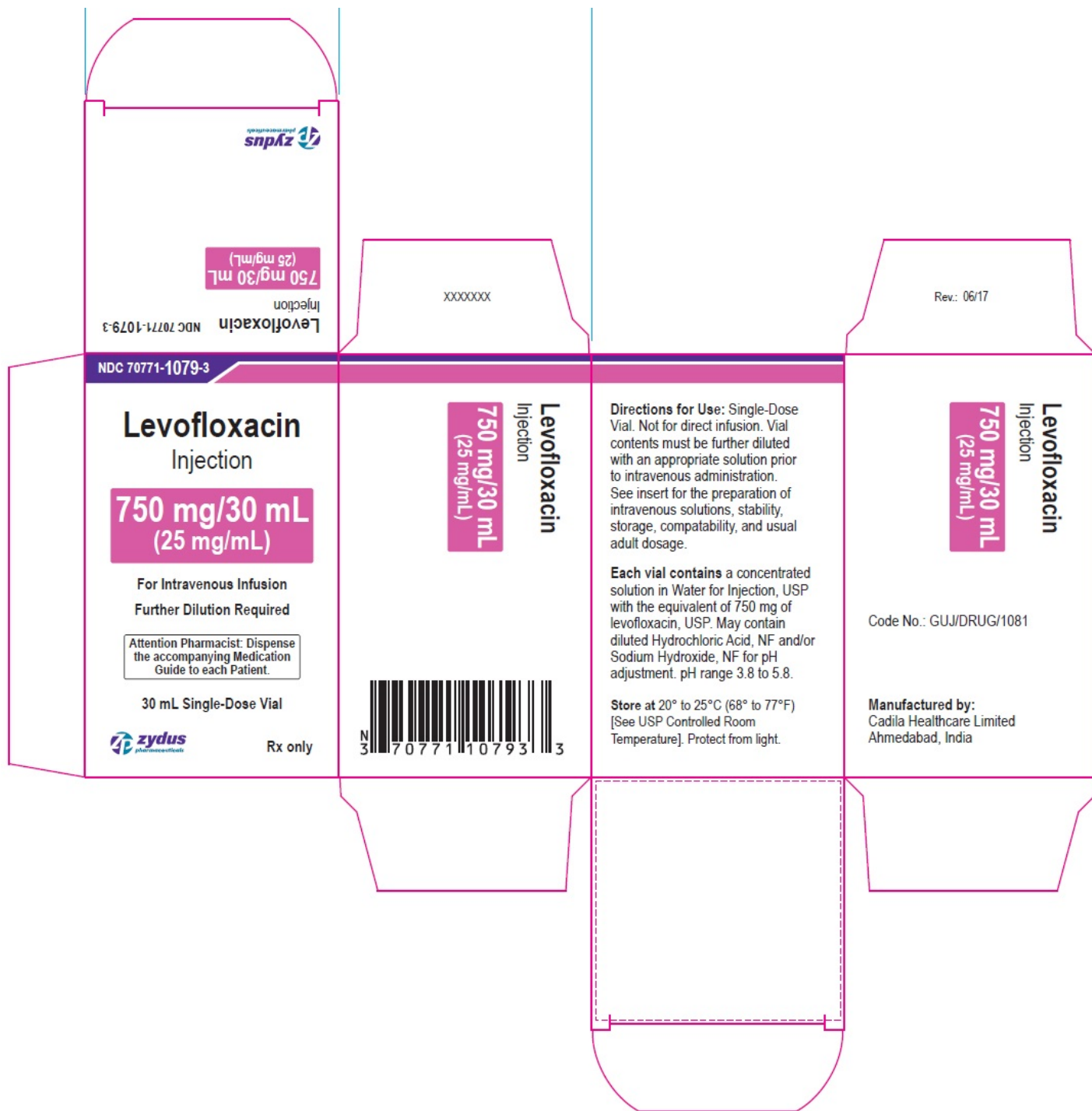
**Further Dilution Required**

**Attention Pharmacist: Dispense the accompanying Medication Guide to each patient.**

**30 mL Single-Dose Vial**

**Rx only**

**zydus pharmaceuticals**



## LEVOFLOXACIN

levofloxacin injection, solution

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1079
<b>Route of Administration</b>	INTRAVENOUS		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>LEVOFLOXACIN</b> (UNII: 6GNT3Y5LMF) (LEVOFLOXACIN ANHYDROUS - UNII:RIX4E89Y14)		LEVOFLOXACIN ANHYDROUS	25 mg in 1 mL	
<b>Inactive Ingredients</b>				
		<b>Ingredient Name</b>	<b>Strength</b>	
		<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)		
		<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)		
		<b>WATER</b> (UNII: 059QF0KO0R)		
<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:70771-1079-2	20 mL in 1 VIAL; Type 0: Not a Combination Product	08/01/2017	
2	NDC:70771-1079-3	30 mL in 1 VIAL; Type 0: Not a Combination Product	08/01/2017	
<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	ANDA205968	08/01/2017		

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1079) , MANUFACTURE(70771-1079)

Revised: 10/2023

Zydus Lifesciences Limited