

LEVOFLOXACIN- levofloxacin injection, solution
Cadila Healthcare Limited

LEVOFLOXACIN INJECTION

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

The image shows a rectangular label for a single-dose vial of Levofloxacin Injection. The label is primarily purple and white. On the left side, there is a vertical barcode with the number (01)00370771107926 printed vertically. The main text on the label includes: 'NDC 70771-1079-2' at the top; 'Levofloxacin Injection' in large font; '500 mg/20 mL (25 mg/mL)' in a purple box; 'For Intravenous Infusion'; 'Attention Pharmacist: Dispense the accompanying Medication Guide to each Patient.'; '20 mL Single-Dose Vial'; the Zydus Pharmaceuticals logo; and 'Rx only'. On the right side, it says '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', and 'Rev: 06/17 XXXXXX'. At the bottom right, there are fields for 'Lot:' and 'Exp:' with a dashed box around them and an arrow pointing to the Lot field.

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

NDC 70771-1079-2

Levofloxacin

Injection

500 mg/20 mL

(25 mg/mL)

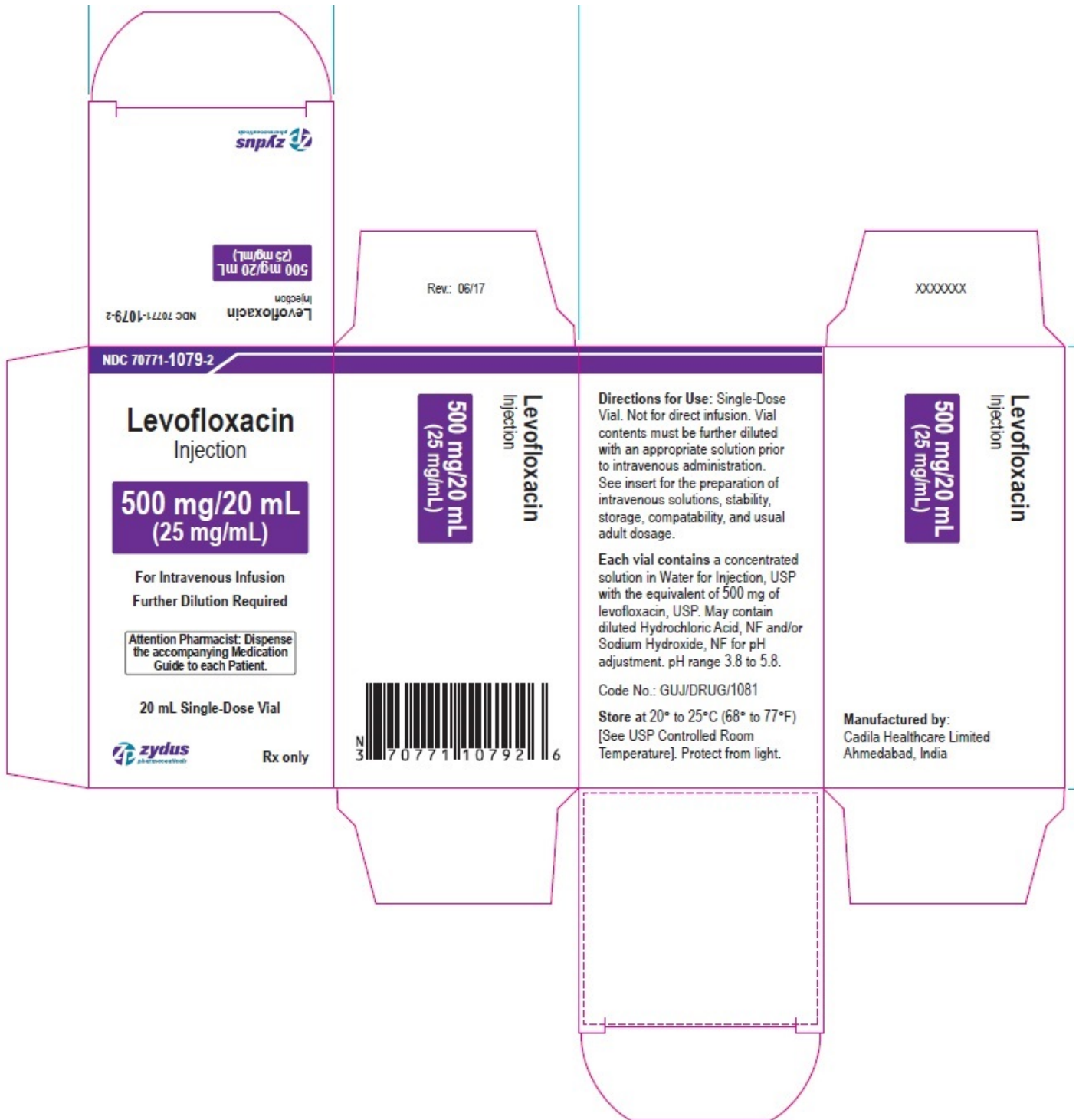
For Intravenous Infusion

Further Dilution Required

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

20 mL Single-Dose Vial

Rx only



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

(01)00370771107933

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, compatibility, and usual adult dosage.

Each vial contains a concentrated solution in Water for Injection, USP with the equivalent of 750 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.

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

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

Code No.: GUJIDRUG/1081

Manufactured by:
Cadila Healthcare Limited
Ahmedabad, India

Rev : 06/17
XXXXXX

Lot: _____

Exp: _____

zydus
pharmaceuticals

Rx only

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

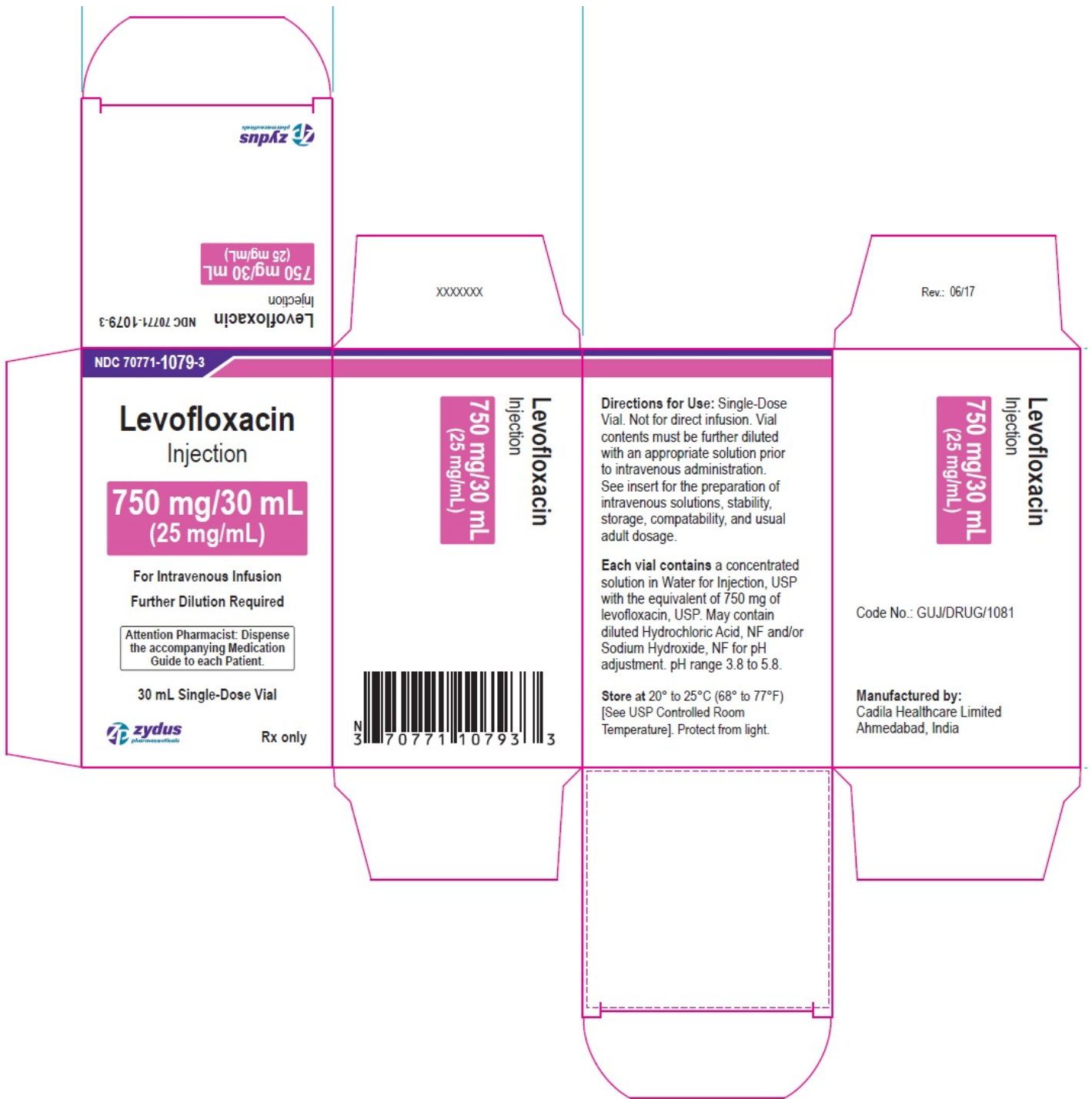
Further Dilution Required

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

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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LEVOFLOXACIN (UNII: 6GNT3Y5LMF) (LEVOFLOXACIN ANHYDROUS - UNII:RIX4E89Y14)	LEVOFLOXACIN ANHYDROUS	25 mg in 1 mL
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Inactive Ingredients

Ingredient Name	Strength
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA205968	08/01/2017	

Labeler - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (918596198)

Establishment

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

Revised: 10/2020

Cadila Healthcare Limited