LEVOFLOXACIN - levofloxacin injection, solution
Zydus Lifesciences 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)

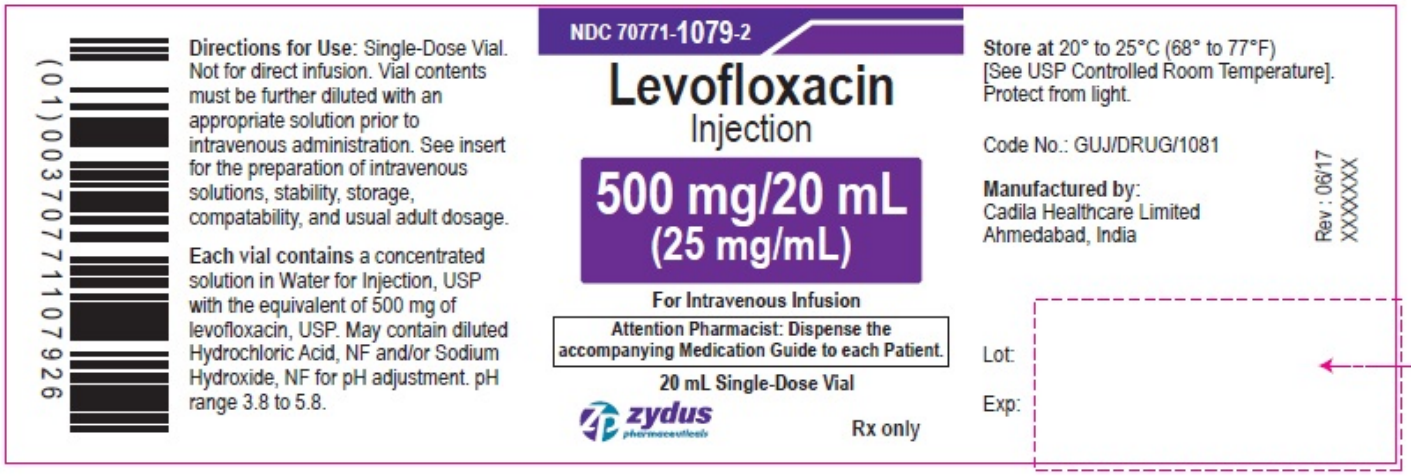
For Intravenous Infusion

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

20 mL Single-Dose Vial

Rx only

zydus pharmaceuticals



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

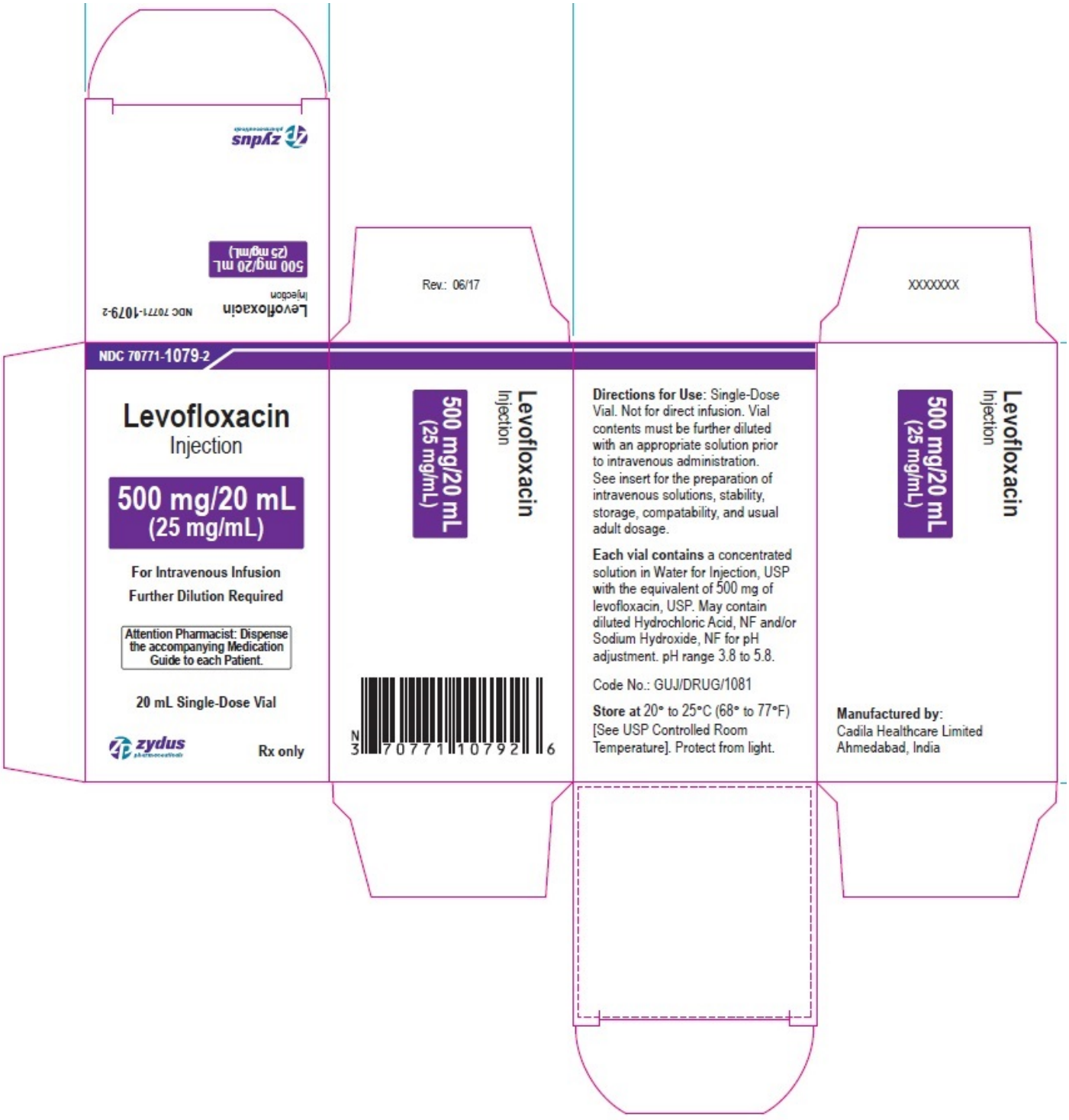
Further Dilution Required

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

20 mL Single-Dose Vial

Rx only

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)

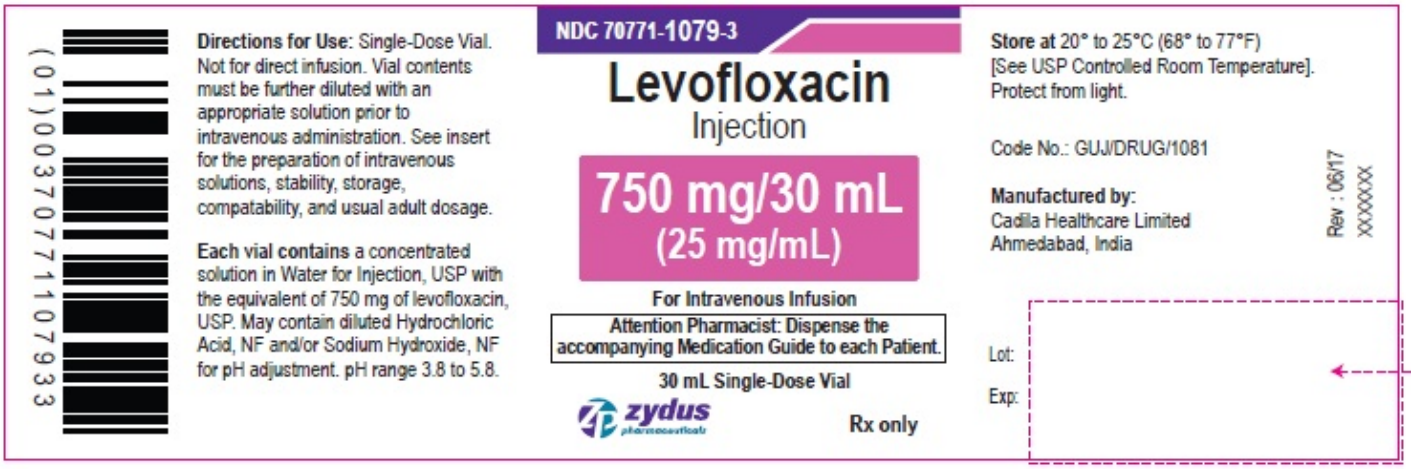
For Intravenous Infusion

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

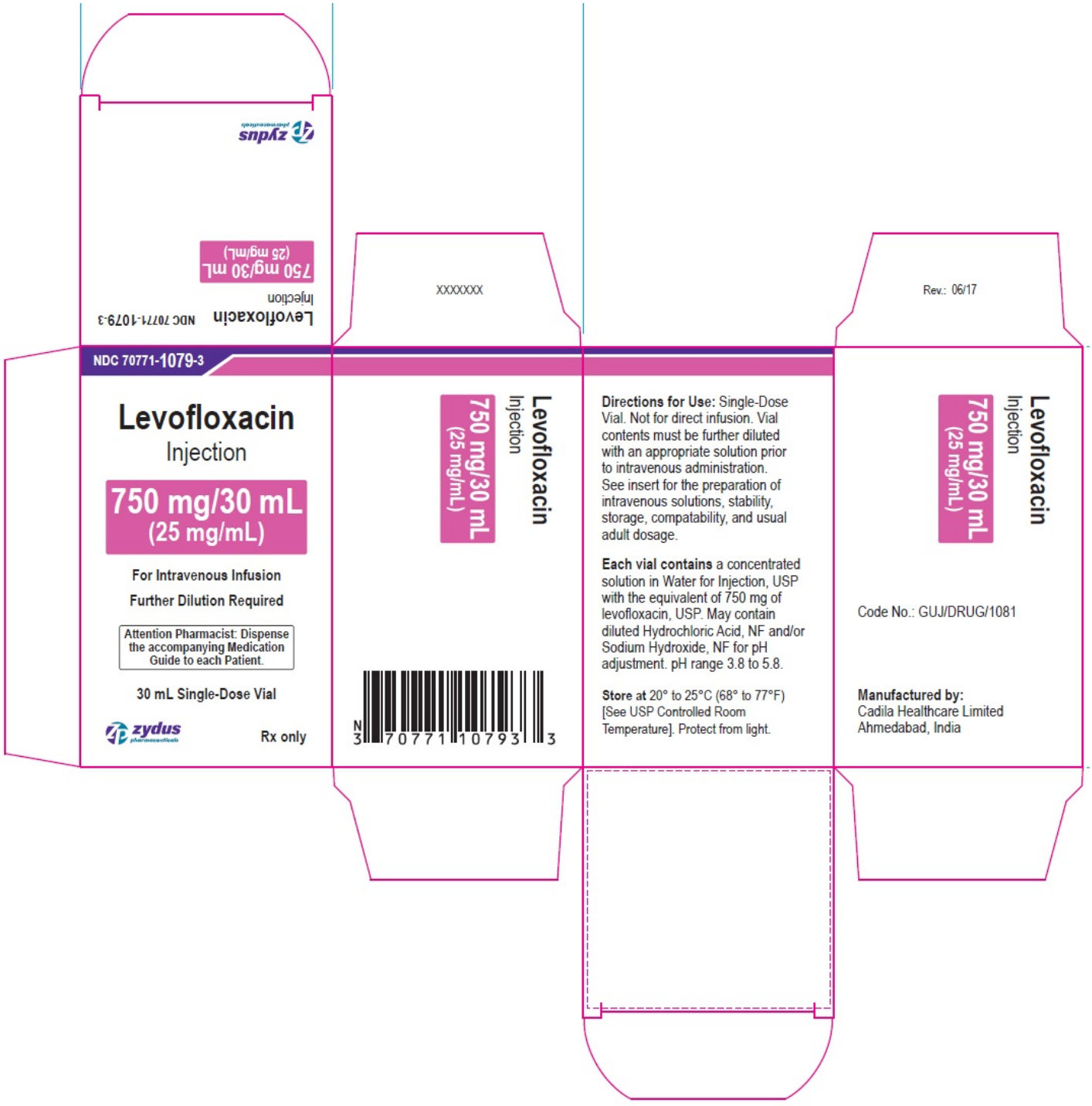
Further Dilution Required

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

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
LEVOFLOXACIN (UNII: 6GNT3Y5LMF) (LEVOFLOXACIN ANHYDROUS - UNII:RIX4E89Y14)	LEVOFLOXACIN ANHYDROUS	25 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

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 - 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: 10/2022 Zydus Lifesciences Limited