

ACYCLOVIR - acyclovir injection, solution
Zydus Lifesciences Limited

Acyclovir Sodium Injection

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

PACKAGE LABEL - PRINCIPAL DISPLAY - 10 mL Single-Use Container Label

NDC 70771-**1383**-1

Acyclovir Sodium Injection

500 mg/10 mL*

(50 mg/mL)

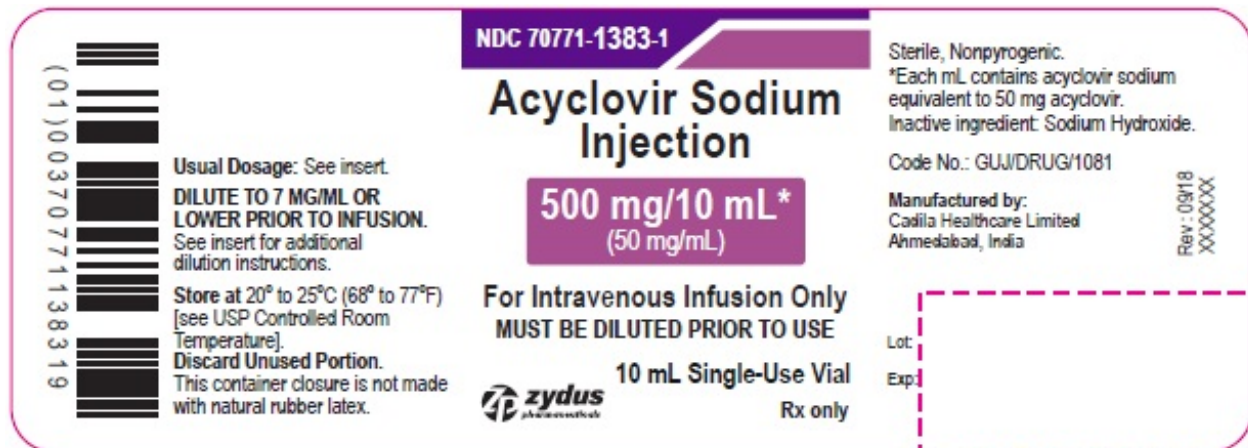
For Intravenous Infusion Only

MUST BE DILUTED PRIOR TO USE

10 mL Single-Use Vial

Rx only

zydus pharmaceuticals



PACKAGE LABEL - PRINCIPAL DISPLAY - 10 mL Single-Use Carton Label

NDC 70771-**1383**-6

Acyclovir Sodium Injection

500 mg/10 mL*

(50 mg/mL)

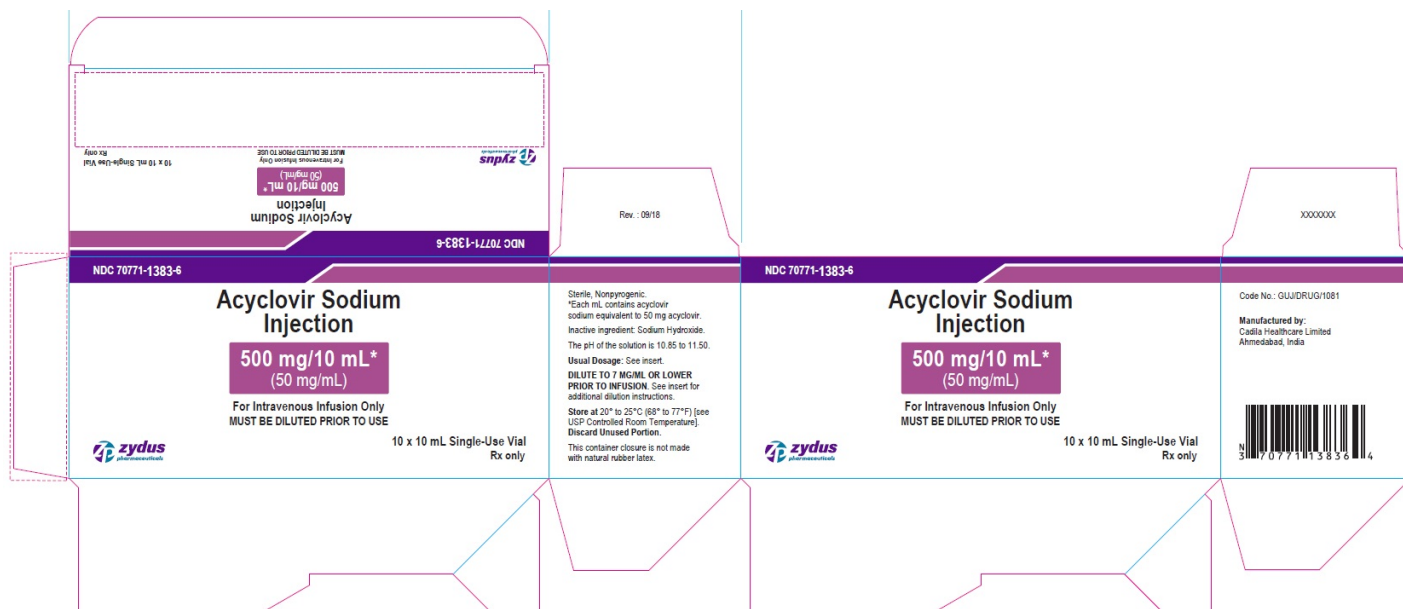
For Intravenous Infusion Only

MUST BE DILUTED PRIOR TO USE

10 x 10 mL Single-Use Vial

Rx only

zydus pharmaceuticals



PACKAGE LABEL - PRINCIPAL DISPLAY - 20 mL Single-Use Container Label

NDC 70771-**1384-1**

Acyclovir Sodium Injection

1000 mg/20 mL*

(50 mg/mL)

For Intravenous Infusion Only

MUST BE DILUTED PRIOR TO USE

20 mL Single-Use Vial

Rx only

zydus pharmaceuticals



(01)00370771138418
 18 4 1 3 8 4 1 1 7 0 7 3 0 0 1

Usual Dosage: See insert.

DILUTE TO 7 MG/ML OR LOWER PRIOR TO INFUSION.
See insert for additional dilution instructions.

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

Discard Unused Portion.
This container closure is not made with natural rubber latex.

NDC 70771-1384-1

Acyclovir Sodium Injection

1000 mg/20 mL*
(50 mg/mL)

For Intravenous Infusion Only
MUST BE DILUTED PRIOR TO USE

20 mL Single-Use Vial
Rx only



Sterile, Nonpyrogenic.
*Each mL contains acyclovir sodium equivalent to 50 mg acyclovir.
Inactive ingredient: Sodium Hydroxide.

Code No.: GUJ/DRUG/1081

Manufactured by:
Cadila Healthcare Limited
Ahmedabad, India

Rev : 09/18
XXXXXX

Lot:

Exp:

PACKAGE LABEL - PRINCIPAL DISPLAY - 20 mL Single-Use Carton Label

NDC 70771-**1384-6**

Acyclovir Sodium Injection

1000 mg/20 mL*

(50 mg/mL)

For Intravenous Infusion Only

MUST BE DILUTED PRIOR TO USE

10 x 20 mL Single-Use Vial

Rx only

zydus pharmaceuticals

ACYCLOVIR
acyclovir injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1383
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACYCLOVIR SODIUM (UNII: 927L42J563) (ACYCLOVIR - UNII:X4HES1O11F)	ACYCLOVIR	50 mg in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1383-6	10 in 1 CARTON	11/27/2018	
1	NDC:70771-1383-1	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206535	11/27/2018	

ACYCLOVIR

acyclovir injection, solution

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WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1384-6	10 in 1 CARTON	11/27/2018	
1	NDC:70771-1384-1	20 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206535	11/27/2018	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1383, 70771-1384) , MANUFACTURE(70771-1383, 70771-1384)

Revised: 10/2022

Zydus Lifesciences Limited