

DOXORUBICIN HYDROCHLORIDE- doxorubicin hydrochloride injectable, liposomal
Cadila Healthcare Limited

DOXOrubicin Hydrochloride Liposome Injection

SPL UNCLASSIFIED

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

20 mg/10 mL Container Label

NDC 49315-008-03

DOXOrubicin Hydrochloride Liposome Injection

20 mg/10 mL

(2 mg/mL)

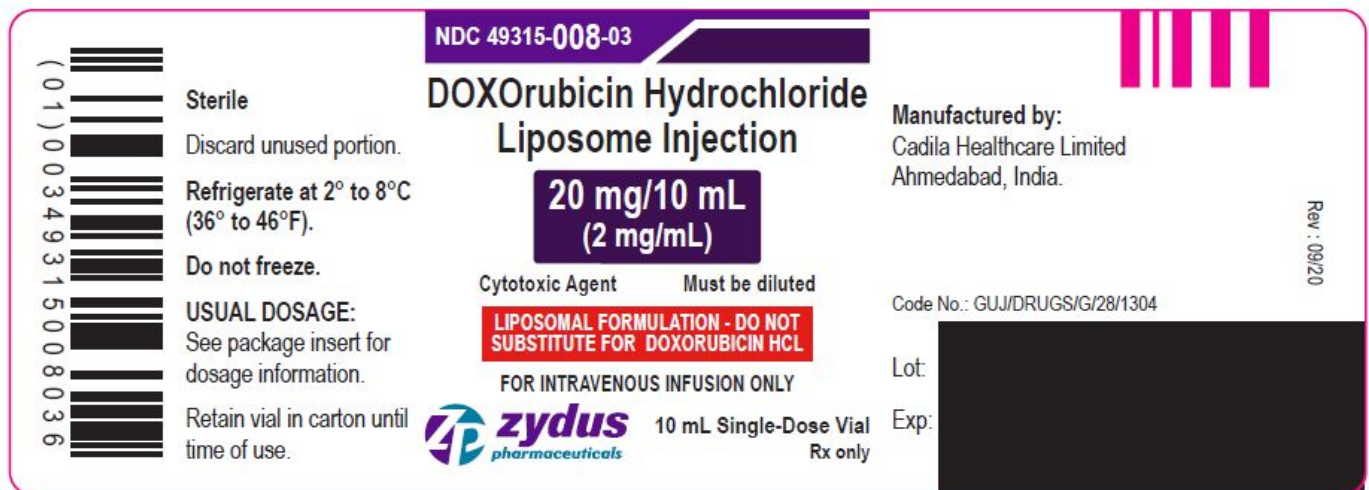
Cytotoxic Agent

Must be diluted

LIPOSOMAL FORMULATION – DO NOT SUBSTITUTE FOR DOXORUBICIN HCL
FOR INTRAVENOUS INFUSION ONLY

10 mL Single-Dose Vial

Rx only



20 mg/10 mL Carton Label

NDC 49315-008-03

DOXOrubicin Hydrochloride Liposome Injection

20 mg/10 mL

(2 mg/mL)

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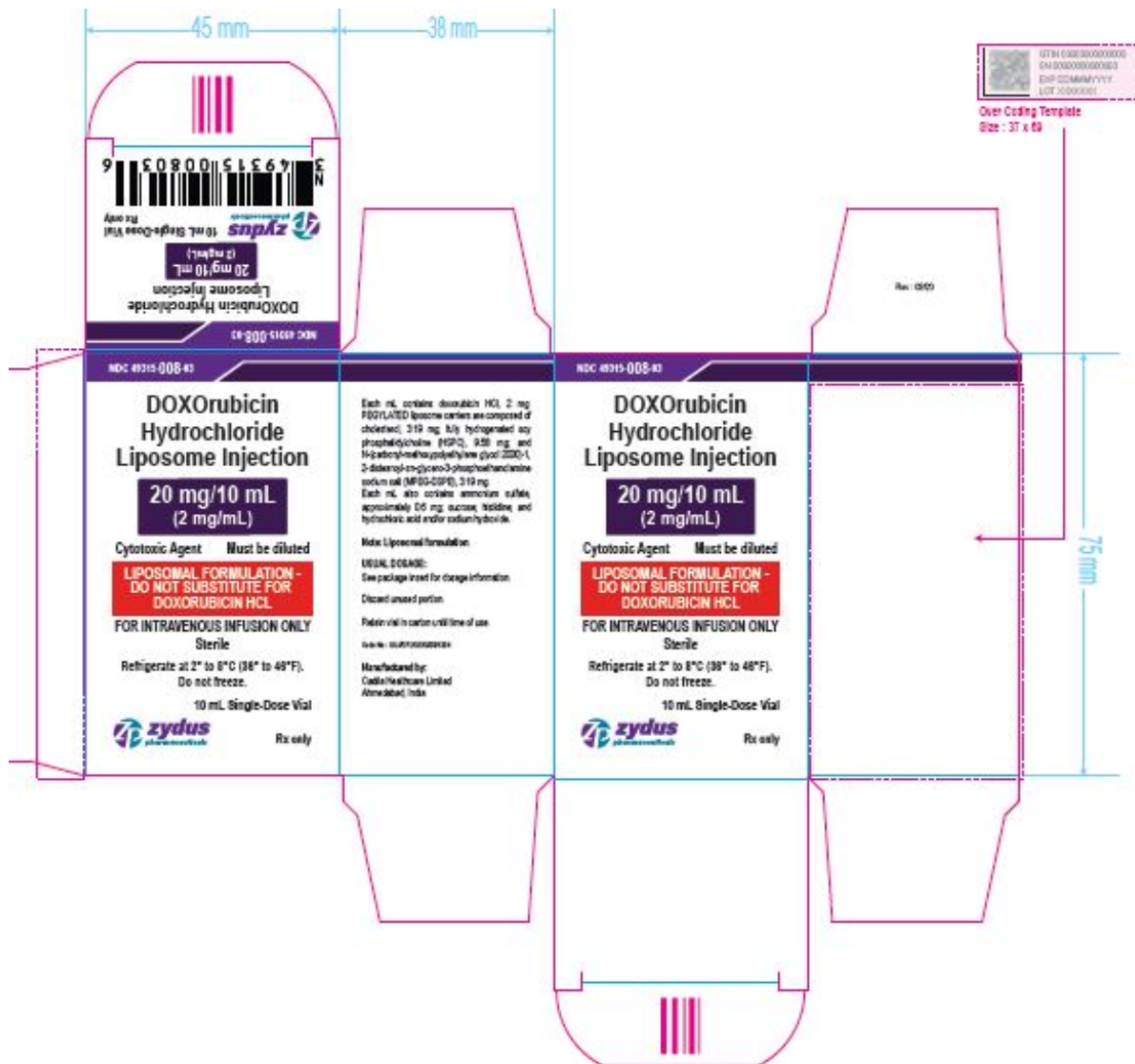
Sterile

Refrigerate at 2° to 8° (36° to 46°)

Do not freeze

10 mL Single-Dose Vial

Rx only



50 mg/25 mL Container Label

NDC 49315-009-07

DOXOrubicin Hydrochloride Liposome Injection

50 mg/25 mL

(2 mg/mL)

Cytotoxic Agent

Must be diluted

LIPOSOMAL FORMULATION – DO NOT SUBSTITUTE FOR DOXORUBICIN HCL

FOR INTRAVENOUS INFUSION ONLY

25 mL Single-Dose Vial

Rx only

(01)00349315009071

NDC 49315-009-07

DOXOrubicin Hydrochloride Liposome Injection

50 mg/25 mL (2 mg/mL)

Cytotoxic Agent Must be diluted

LIPOSOMAL FORMULATION - DO NOT SUBSTITUTE FOR DOXORUBICIN HCL

FOR INTRAVENOUS INFUSION ONLY

zydus pharmaceuticals

25 mL Single-Dose Vial Rx only

Manufactured by:
Cadila Healthcare Limited
Ahmedabad, India.

Code No.: GUJ/DRUGS/G/28/1304

Rev: 09/20

Lot: [REDACTED]

Exp: [REDACTED]

50 mg/25 mL Carton Label

NDC 49315-009-07

DOXOrubicin Hydrochloride Liposome Injection

50 mg/25 mL

(2 mg/mL)

Cytotoxic Agent Must be diluted

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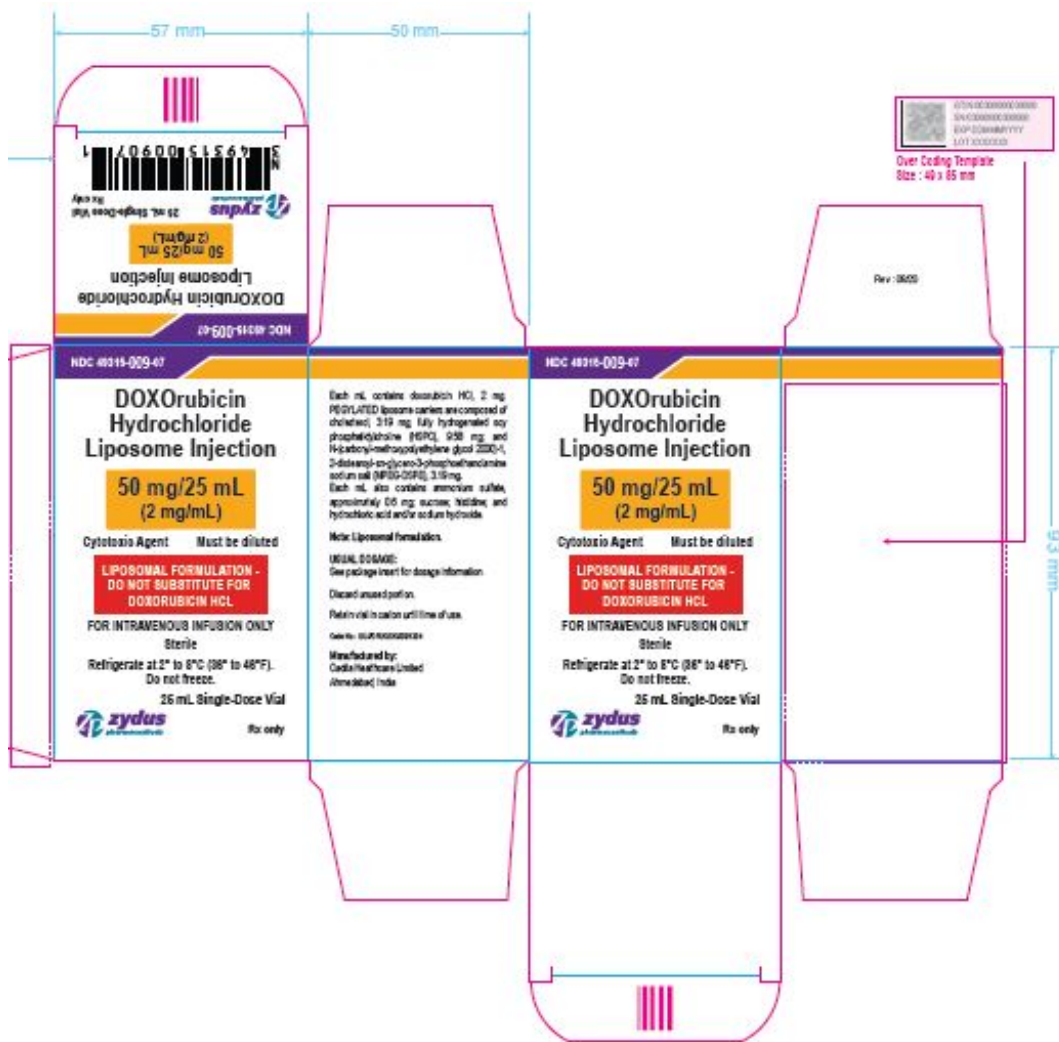
Sterile

Refrigerate at 2° to 8° (36° to 46°)

Do not freeze

25 mL Single-Dose Vial

Rx only



DOXORUBICIN HYDROCHLORIDE

doxorubicin hydrochloride injectable, liposomal

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:49315-008
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXORUBICIN HYDROCHLORIDE (UNII: 82F2G7BL4E) (DOXORUBICIN - UNII:80168379AG)	DOXORUBICIN HYDROCHLORIDE	2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
N-(CARBONYL-METHOXYPOLYETHYLENE GLYCOL 2000)-1,2-DISTEAROYL-SN-GLYCERO-3-PHOSPHOETHANOLAMINE, SODIUM SALT (UNII: 3L6NN8ZZKU)	3.19 mg in 1 mL
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	9.58 mg in 1 mL

CHOLESTEROL (UNII: 97C5T2UQ7J)	3.19 mg in 1 mL
AMMONIUM SULFATE (UNII: SU46BAM238)	0.6 mg in 1 mL
SUCROSE (UNII: C151H8M554)	
HISTIDINE (UNII: 4QD397987E)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49315-008-03	1 in 1 CARTON	09/14/2020	
1		10 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA212299	09/14/2020	

DOXORUBICIN HYDROCHLORIDE

doxorubicin hydrochloride injectable, liposomal

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HISTIDINE (UNII: 4QD397987E)	

HYDROCHLORIC ACID (UNII: QTT17582CB)

SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49315-009-07	1 in 1 CARTON	09/14/2020	
1		25 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA212299	09/14/2020	

Labeler - Cadila Healthcare Limited (650348852)

Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		650348852	ANALYSIS(49315-008, 49315-009) , MANUFACTURE(49315-008, 49315-009)

Revised: 9/2020

Cadila Healthcare Limited