

LACOSAMIDE- lacosamide injection
Zydus Lifesciences Limited

LACOSAMIDE injection, for intravenous use, CV

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1682-1

Lacosamide Injection, USP 200 mg/20 mL (10 mg/mL); CV

For Intravenous Use Only

20 mL single-dose vial

Rx only

3707711168217

Medication Guide available at
www.zydususa.com/medguides
or call 1-877-993-8779.

GUJ/DRUGS/G/28/1609

Manufactured by:
Zydus Lifesciences Ltd.
Vadodara, India

NDC 70771-1682-1

Lacosamide (V)
Injection, USP

200 mg/20 mL
(10 mg/mL)

For Intravenous Use Only
20 mL single-dose vial

zydus

Rx only

USUAL DOSAGE: See package insert for dosage information.
Discard unused portion.
Store at controlled room temperature.
KEEP OUT OF REACH OF CHILDREN.
This container closure is not made with natural rubber latex.

Rev.: 06/22

Lot:
Exp:

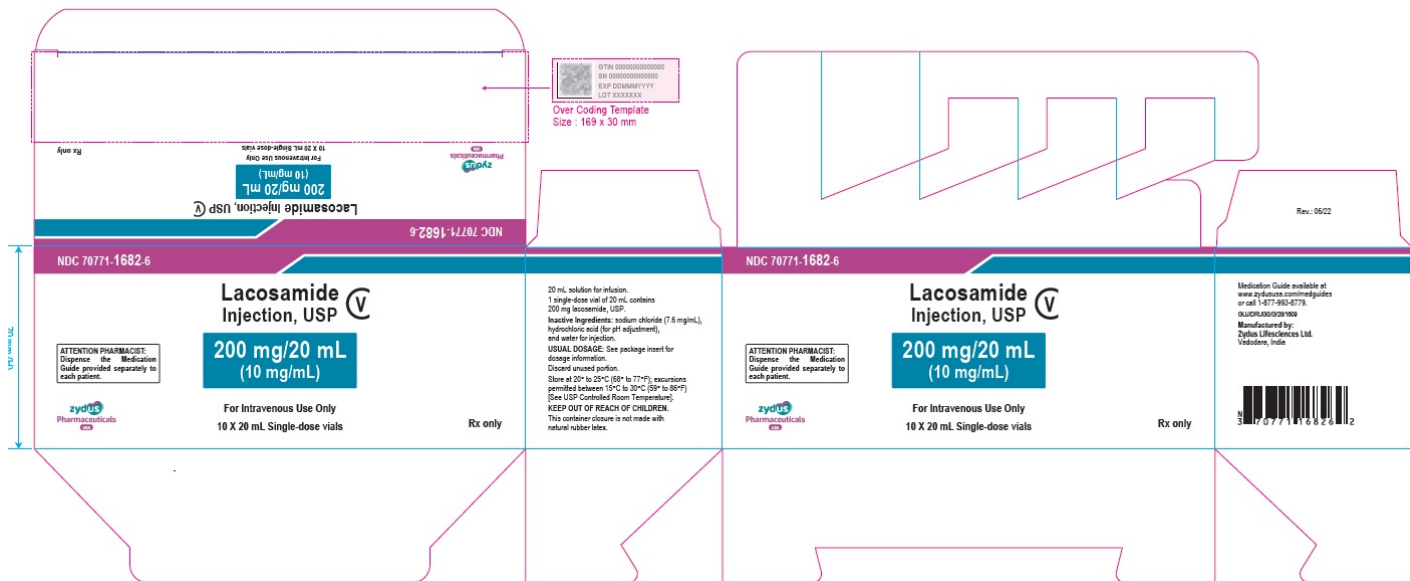
NDC 70771-1682-6

Lacosamide Injection, USP 200 mg/20 mL (10 mg/mL); CV

For Intravenous Use Only

10 X 20 mL Single-dose vials

Rx only



LACOSAMIDE

lacosamide injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1682
Route of Administration	INTRAVENOUS	DEA Schedule	CV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LACOSAMIDE (UNII: 563KS2PQY5) (LACOSAMIDE - UNII:563KS2PQY5)	LACOSAMIDE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1682-6	10 in 1 CARTON	06/29/2022	
1	NDC:70771-1682-1	20 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209465	06/29/2022	

Labeler - Zyduz Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zyduz Lifesciences Limited		873671928	MANUFACTURE(70771-1682) , ANALYSIS(70771-1682)

Revised: 10/2023

Zyduz Lifesciences Limited