

TRANEXAMIC ACID - tranexamic acid injection
Zydus Lifesciences Limited

Tranexamic Acid Injection 100 mg/mL, 10 mL

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

CONTAINER LABEL

NDC 70771-1085-1

Tranexamic Acid Injection

1000 mg/10 mL

(100 mg/mL)

Solution for Intravenous Injection

Discard any remaining portion after single use.

10 mL Single-Dose Vial

Rx only

zydus pharmaceuticals

NDC 70771-1085-1

Tranexamic Acid Injection

1000 mg/10 mL
(100 mg/mL)

Solution for Intravenous Injection
Discard any remaining portion after single use.
10 mL Single-Dose Vial

Rx only

Code No.: GUJIDRUG/1081

Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

The vial stopper is not made with natural rubber latex.

zydus pharmaceuticals

DOSAGE AND USE: See accompanying prescribing information.

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev: 12/18
XXXXXXX

Lot:

Exp:

CARTON LABEL

NDC 70771-1085-6

Tranexamic Acid Injection

1000 mg/10 mL

(100 mg/mL)

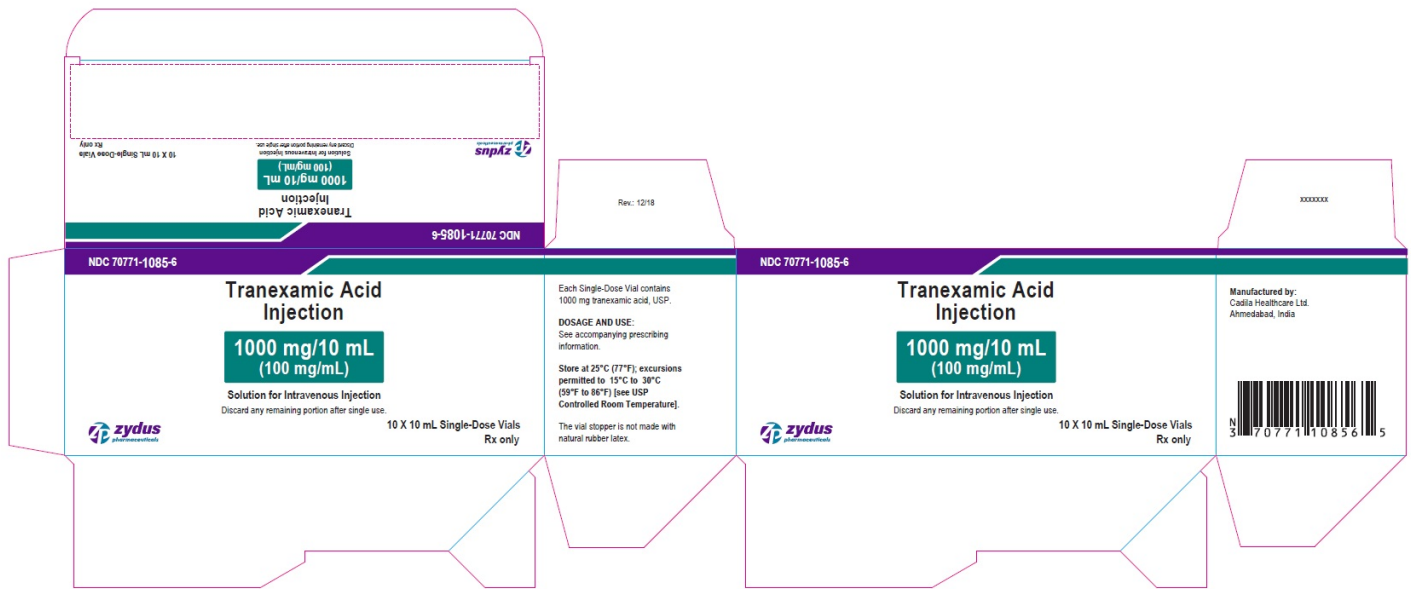
Solution for Intravenous Injection

Discard any remaining portion after single use.

10 X 10 mL Single-Dose Vials

Rx only

zydus pharmaceuticals



TRANEXAMIC ACID

tranexamic acid injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1085
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRANEXAMIC ACID (UNII: 6T84R30KC1) (TRANEXAMIC ACID - UNII:6T84R30KC1)	TRANEXAMIC ACID	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1085-6	10 in 1 CARTON	10/04/2017	

1	10 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	ANDA205228	10/04/2017	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1085) , MANUFACTURE(70771-1085)

Revised: 11/2022

Zydus Lifesciences Limited