

**TRANEXAMIC ACID- tranexamic acid injection, solution**  
**Emcure Pharmaceuticals Limited**

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**Rx only**

**INDICATIONS AND USAGE**

Tranexamic acid injection, USP is indicated in patients with hemophilia for short-term use (2 to 8 days) to reduce or prevent hemorrhage and reduce the need for replacement therapy during and following tooth extraction.

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC **14593-318-01**

Tranexamic **Acid Injection, USP**

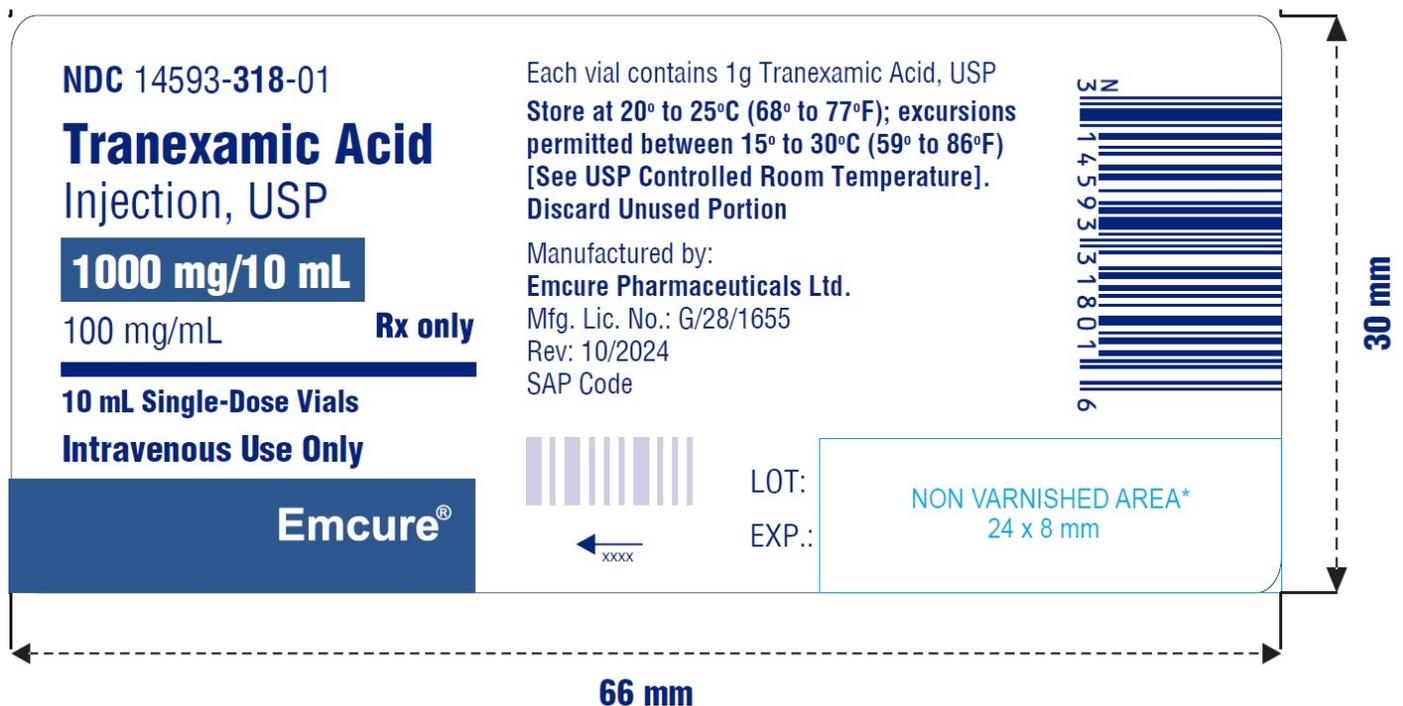
**1000 mg/10 mL**

(100 mg/mL)

**Intravenous Use Only**

**Rx only**

10 mL Single-Dose Vial



**TRANEXAMIC ACID**  
tranexamic acid injection, solution

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:14593-318
<b>Route of Administration</b>	INTRAVENOUS		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>TRANEXAMIC ACID</b> (UNII: 6T84R30KC1) (TRANEXAMIC ACID - UNII:6T84R30KC1)	TRANEXAMIC ACID	1 g in 10 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:14593-318-01	10 in 1 CARTON	10/28/2024	
1		10 mL in 1 VIAL; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA203521	10/28/2024	

**Labeler** - Emcure Pharmaceuticals Limited (916921919)

**Registrant** - Emcure Pharmaceuticals Limited (916921919)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Emcure Pharmaceuticals Limited		675467924	ANALYSIS(14593-318) , MANUFACTURE(14593-318) , PACK(14593-318) , LABEL(14593-318)

Revised: 10/2024

Emcure Pharmaceuticals Limited