

# Tranexamic Acid RTU



**Tranexamic Acid Ready-to-Use for infusion, eliminating the need for reconstitution in most settings (Generic U.S. / Reformulating in EU)**

**Core Driver**

**Worldwide Markets**

## **ABOUT**

Ready-to-use intravenous formulation of tranexamic acid designed to simplify current practice by reducing or eliminating the need for reconstitution and dilution prior to administration. Unlike concentrated products that usually require preparation by qualified medical professionals, the RTU formulation enables immediate administration. This provides a convenient and practical option for use in surgical procedures and other clinical settings where reduced preparation time, lower handling complexity, and improved workflow efficiency are important advantages.

## **STAGE**

In June 2025, Hyloris' exclusive U.S. partner received FDA approval of its Abbreviated New Drug Application (ANDA) for an intravenous, ready-to-use (RTU) formulation of tranexamic acid, supplied as 10 mg/mL in 100 mL vials. The U.S. launch is planned for the first half of 2026. In Europe, the product is being developed under a value-added medicine approach, reflecting its meaningful practical and clinical advantages versus concentrated reference medicinal products, and is under registration in several countries.

## **INDICATION**

In patients with hemophilia, for short term use to reduce or prevent hemorrhage and reduce the need for replacement therapy during and following tooth extraction. In practice it is mostly used for prevention and treatment of excessive bleeding.

## **BENEFIT**

A ready-to-use intravenous formulation that eliminates the need for reconstitution, offering a convenient, time-saving alternative that may streamline treatment and improve patient outcomes.

## **IP RIGHTS / EXCLUSIVITY**

Granted U.S. (expiry 2 Dec 2039) and BE (expiry 17 June 2039) patents; Ready-to-Use Tranexamic Acid intravenous solution.

# Forward-Looking Statements



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# Value Starts Here

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Hyloris Pharmaceuticals SA - 2026



HQ: Boulevard Patience Et Beaujonc N°3/1  
4000 Liège, Belgium



+32(0)4 346 02 07



[contact@hyloris.com](mailto:contact@hyloris.com)  
[investorrelations@hyloris.com](mailto:investorrelations@hyloris.com)

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