Traxlink 500 Injection

Tranexamic Acid (500mg) Injection

Category: Antifibrinolytic Agent

Dosage Form: Injectable Solution

Description:

Tranexamic Acid (500mg) Injection is a synthetic antifibrinolytic agent that helps to prevent or reduce excessive bleeding. It works by inhibiting the enzyme plasminogen activator, thus preventing the conversion of plasminogen to plasmin. Plasmin is responsible for breaking down fibrin, a protein that is essential for blood clotting. By preventing plasmin formation, Tranexamic Acid stabilizes the fibrin clot, reducing unwanted bleeding in conditions like surgery, trauma, or menstrual disorders.

This injection is commonly used in hospital settings for the management of severe bleeding and during or after surgeries, including dental procedures, cardiac surgery, and obstetric procedures. It is also used in cases of heavy menstrual bleeding (menorrhagia) and bleeding associated with trauma.

Composition:

- Active Ingredient:
 - Tranexamic Acid 500mg per 5mL
- Excipients:

- Water for injection (q.s. to 5mL)
- Sodium chloride (for isotonicity)
- pH adjusters (e.g., sodium hydroxide, hydrochloric acid) for maintaining the correct pH of the solution.

Indications:

- 1. Excessive Menstrual Bleeding (Menorrhagia): Tranexamic acid is effective in controlling abnormal bleeding during menstruation by stabilizing blood clots.
- 2. Postoperative Bleeding: Used to prevent or reduce bleeding after surgical procedures such as cardiac surgery, orthopedic surgeries, dental procedures, or cesarean section.
- 3. Trauma or Injury: To control bleeding in traumatic injuries, particularly where there is significant blood loss.
- 4. Nasal or Otologic Bleeding: For cases of epistaxis (nosebleeds) or bleeding related to ear or sinus surgeries.
- 5. Dental Surgery: For the control of bleeding in dental procedures, especially in patients with bleeding disorders.
- 6. Bleeding in Hemophilia or Other Bleeding Disorders: Used in conjunction with other treatment regimens in hemophilic patients or those with other clotting disorders.

Dosage and Administration:

- Adults:
 - For Heavy Menstrual Bleeding: The typical dosage is 500mg (5mL) every 8 hours for up to 5 days during menstruation. The exact duration and dosage should be determined by the doctor.
 - For Surgical Bleeding Control: 500mg (5mL) injected intravenously before, during, and after surgery. The dosage and frequency may vary based on the type of surgery, patient condition, and bleeding severity. It is commonly given as an IV bolus or as an IV infusion.
 - For Trauma: 500mg (5mL) IV injection, typically given immediately following injury or trauma, and repeated as necessary based on clinical assessment.
 - For Dental Procedures: A 500mg dose is administered prior to the procedure and repeated as necessary postprocedure.
- Pediatric Patients:
 - For Children: The dosage should be adjusted based on the child's weight and clinical condition, and it should be determined by a healthcare provider.
- Administration Method:
 - Tranexamic acid injection is typically administered intravenously (IV), either as an IV bolus or IV infusion.
 - The IV bolus is generally administered over 5–10

minutes, while an infusion may be given over a longer period.

• The injection may be diluted with saline solution before administration, depending on the protocol or clinical situation.

Mechanism of Action:

Tranexamic acid is an antifibrinolytic agent that works by inhibiting the activation of plasminogen to plasmin. Plasmin is an enzyme that breaks down fibrin, the main protein component of blood clots. By preventing plasmin formation, Tranexamic Acid helps maintain the integrity of the clot, preventing excessive bleeding and promoting the stabilization of existing clots.

Contraindications:

- Hypersensitivity to Tranexamic Acid or any component of the injection.
- Active Thromboembolic Disease: This includes conditions such as deep vein thrombosis (DVT), pulmonary embolism (PE), or stroke.
- Severe Renal Impairment: Use caution in patients with severe kidney disease as the drug is excreted through the kidneys, and impaired kidney function can lead to drug accumulation and adverse effects.
- Subarachnoid Hemorrhage: Tranexamic acid should be avoided in patients with active or recent subarachnoid hemorrhage (bleeding in the brain).
- History of Thrombotic Events: Contraindicated in patients who

have had blood clots, especially without prophylactic anticoagulation.

Warnings and Precautions:

- 1. Risk of Thrombosis: Tranexamic acid may increase the risk of blood clots in susceptible patients. It should be used cautiously in patients with a history of thrombosis, heart disease, or those undergoing major surgery.
- 2. Renal Impairment: Monitor kidney function in patients with mild-tomoderate renal impairment. Dosage adjustments may be necessary.
- 3. Pregnancy and Lactation: Tranexamic acid should be used during pregnancy only if the potential benefit justifies the risk to the fetus (Category C). Use during breastfeeding should be done with caution.
- 4. Hypertension: Tranexamic acid should be used cautiously in patients with high blood pressure as it can affect blood clotting and may increase thrombotic risk.
- 5. Blood Clotting Disorders: Care should be taken when administering this drug to patients with conditions like hemophilia or other clotting disorders, and it should not replace traditional clotting factor therapies.

Adverse Effects:

Common Side Effects:

• Gastrointestinal disturbances, such as nausea, vomiting, and diarrhea.

- Headache, dizziness, or lightheadedness.
- Fatigue or tiredness.

Serious Side Effects:

- Thromboembolic events: Including deep vein thrombosis, pulmonary embolism, or stroke.
- Hypotension (low blood pressure) with rapid intravenous administration.
- Allergic reactions: Rash, itching, or more severe symptoms like swelling of the face, lips, tongue, or throat, which may cause difficulty breathing (anaphylaxis).
- Kidney dysfunction: In cases of severe renal impairment, prolonged use of the drug may lead to kidney damage.

If any of these serious side effects occur, immediate medical attention is required.

Drug Interactions:

- Anticoagulants (Blood Thinners): Tranexamic acid may enhance the effects of anticoagulants, increasing the risk of clotting issues.
- Hormonal Contraceptives: Combined with Tranexamic acid, oral contraceptives may further increase the risk of thrombosis.
- Cyclosporine: Tranexamic acid may interact with cyclosporine, a drug used to prevent organ rejection, and alter its metabolism.

Storage Instructions:

- Store at room temperature (15°C 30°C).
- Protect from light and moisture.
- Do not freeze the solution.
- Keep out of reach of children.

Key Points:

- Tranexamic Acid (500mg) Injection is used for the control of excessive bleeding, particularly during surgery, trauma, and certain menstrual disorders.
- It helps to stabilize blood clots and prevent unnecessary breakdown, reducing the risk of hemorrhage.
- It should be used with caution in patients with a history of blood clots, renal issues, and those undergoing major surgeries.
- Always follow the prescribed dosage and administration protocols and consult a healthcare provider before use, especially during pregnancy, breastfeeding, or in the presence of underlying medical conditions.

Consult your healthcare provider for personalized advice and treatment.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd. (An ISO 9001: 2015 Certified Co.) Plot no.: 367-FF, Industrial Area Phase-I, Panchkula-134113 TM: Trademark Applied for