PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

HEXAKAPRON® TABLETS

Composition

Each tablet contains: Tranexamic Acid 500 mg

For information on inactive ingredients in the preparation – see section 6 – "Further Information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended to treat hemorrhage.

Therapeutic group

Promotes blood clotting – antifibrinolytic

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient (tranexamic acid), or to any of the additional ingredients contained in the medicine (see section 6).
- You have serious kidney problems (kidney failure).
- You have an active thromboembolic disease (hypercoagulability of the blood).
- You have a history of venous or arterial thrombosis.
- You have a history of convulsions.
- You are at risk of excessive bleeding as a result of a coagulation disorder called consumption coagulopathy.

Special warnings regarding use of the medicine

Before treatment with Hexakapron, tell the doctor if:

- You have blood in the urine, due to an increased risk of blockage of the urinary tract.
- You have ever had uncontrollable bleeding.
- You have disseminated intravascular coagulation (DIC), a disease where the blood starts to clot throughout the body.
- You are taking, every day and for a long period, a medicine to treat a hereditary disease called angioneurotic edema (HANO). If so, you may need to have routine eye tests and blood tests performed to check liver function.
- You have irregular menstrual periods.
- You have had a thromboembolic event in the past.
- One of your family members has suffered from thromboembolic disease (thrombophilia, hypercoagulability).
- You have kidney disease.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist, especially if you are taking:

- Fibrinolytic medicines (that help to dissolve blood clots), such as streptokinase, since tranexamic acid (the active ingredient in Hexakapron), will prevent the activity of these medicines.
- Oral contraceptives – may increase the risk of formation of blood clots.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you are pregnant or are planning a pregnancy, consult your doctor or pharmacist before taking this medicine.

Important information about some of the ingredients of the medicine

This medicine contains less than 23 mg sodium per tablet and is therefore considered sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

Do not exceed the recommended dose.

Crushing/halving/chewing

The tablet can be halved on the score line.

There is no information regarding crushing or chewing.

Always take the medicine with a glass of water.

If you accidentally take a higher dosage

If you accidentally took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

Taking an overdose of tranexamic acid may cause nausea, vomiting, dizziness or lightheadedness when standing up.

If you forget to take the medicine

If you forgot to take this medicine at the designated time, do not take a double dose to compensate for the forgotten dose. Take the next dose as planned.

Adhere to the treatment regimen as recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Hexakapron may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Eye disorders

Rare side effects (effects that occur in 1-10 in 10,000 users):

- Vision problems, especially in seeing colors
- A blood clot in the eye. This may cause bleeding in the eye or loss of vision

Immune system disorders

Very rare side effects (effects that occur in less than 1 in 10,000 users):

- Including allergic reactions that cause difficulty in breathing or dizziness

Blood vessel disorders

Very rare side effects (effects that occur in less than 1 in 10,000 users):

- Blood clot in the blood vessels (a condition called thrombosis)

Digestive system disorders

Very rare side effects (effects that occur in less than 1 in 10,000 users):

- Nausea
- Vomiting
- Diarrhea

These side effects are generally mild and pass very quickly, but if they continue, tell your doctor or pharmacist.

Skin or subcutaneous tissue disorders

Rare side effects (effects that occur in 1-10 in 10,000 users):

- Itching, redness or swelling of the skin

Nervous system disorders

Side effect of unknown frequency (frequency cannot be determined from the available data):

Convulsions, especially in cases of misuse

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (Exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- **Store in a dry place, below 25°C, in the original package in order to protect from light.**
- Do not discard medicines in the wastewater or household waste. Ask the pharmacist how to dispose of medicines that are not in use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

microcrystalline cellulose, sodium starch glycolate, magnesium stearate, methylcellulose, talc, colloidal silicon dioxide.

What the medicine looks like and the contents of the package

A white, round, flat beveled tablet, engraved "TEVA" on one side and score line on the other.

Each package contains 20 or 30 tablets packed in trays (blister).

Not all package sizes may be marketed.

Name of Manufacturer and License Holder and its Address

Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020.

This leaflet was revised in August 2023 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 016.35.24864

teva

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