EXACYL® 0.5 G / 5 ML

tranexamic acid

Solution for injection I.V.

Please read all of the leaflet carefully before taking this medicine.
- Keep this leaflet you may need to read it again.
- If you have any other questions or doubts, ask your doctor or pharmacist for further information.
- This medicine has been prescribed personally for you. Do not give it to anybody else, even if he/she has identical symptoms since it might cause harm to him/her.

IDENTIFICATION OF THE MEDICINE

Composition for one ampoule

tranexamic acid ..... 0.5 g

Excipients: concentrated hydrochloric acid q.s.pH 7.0 - 7.5, water for injection q.s.f. 5 ml.

Pharmaceutical form and presentation

Solution for IV injection.

Box of 5 ampoules of 5 ml.

Pharmaco-therapeutic class

ANTIFIBRINOLYTIC AGENT

Holder/Distributor

sanofi-aventis france
1-13, boulevard Romain Rolland
75014 Paris - France

Manufacturer

Sanofi Winthrop Industrie
6, boulevard de l'Europe
21800 Quétigny - France

WHEN THIS MEDICINE SHOULD BE USED

This medicine is an antihaemorrhagic agent recommended in the treatment of certain types of bleeding.

ATTENTION!

When this medicine should not be used

This medicine SHOULD not be used in the following cases:

- you have a history of, or are currently suffering from: arterial or venous thromboembolic disease (phlebitis, pulmonary embolism, angina pectoris, myocardial infarction, stroke),
- disseminated intravascular coagulation (serious blood coagulation disorders), serious renal impairment,
- if you have a history of, or are currently suffering from convulsions,
- intraventricular and intrathecal injection, and intracerebral applications (if injections need to be administered within the brain).

WHEN IN DOUBT, IT IS ESSENTIAL TO SEEK ADVICE FROM YOUR DOCTOR OR YOUR PHARMACIST.

Special warnings

Do not administer by intramuscular route.

Do not carry out intrathecal or intraventricular injection, or intracerebral applications (if injections need to be administered within the brain).

Inform your doctor:

- if you have a history of, or are currently suffering from convulsions, or if you are taking antiepileptic medication,
- if you have signs of blood in the urine,
- if you are taking oral contraceptives or hormone replacement treatment for the menopause.

Immediately inform your doctor if the following symptoms develop:

- unusual pain in the legs, weakness in the limbs, chest pain, irregular pulse, sudden shortness of breath, loss of consciousness, confusion,
- unusual severe headaches, dizziness, visual disturbances, slowed speech or loss of speech.

ALWAYS KEEP OUT OF THE REACH OF CHILDREN.

Special precautions for use

The dosage should be adjusted in patients with chronic renal failure.

IF IN DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE BEFORE TAKING ANY MEDICINE.

Drug interactions and other interactions

IN ORDER TO PREVENT POSSIBLE INTERACTIONS BETWEEN SEVERAL MEDICINES, YOU MUST SYSTEMATICALLY INFORM YOUR DOCTOR OR PHARMACIST IF YOU ARE TAKING ANY OTHER MEDICINES.

Pregnancy - Lactation

Pregnancy

It is preferable not to use this medicine during the first trimester of pregnancy. If you discover that you are pregnant during treatment, consult rapidly your doctor who will be able to adapt the treatment to your condition.

Lactation

Breast-feeding is not recommended throughout treatment.

As a general rule, you should always seek advice from your doctor or pharmacist before taking any medication during pregnancy or breast-feeding.

Drivers and machine operators

Drivers and machine operators are warned of the risk of vertigo attached to the use of this medicine.

HOW TO USE THIS MEDICINE

Dosage

In adults, do not exceed 4 g per 24 hours.

IN ANY CASE, STRICTLY FOLLOW YOUR DOCTOR'S PRESCRIPTION.

Method and route of administration

Strictly by slow intravenous route.

Frequency and time of administration

To be divided into 2 to 3 injections per 24 hours.

Treatment duration

IN ANY CASE, STRICTLY FOLLOW YOUR DOCTOR'S PRESCRIPTION.

UNWANTED AND UNPLEASANT EFFECTS

LIKE ALL ACTIVE PRODUCTS, THIS MEDICINE MAY, IN CERTAIN PEOPLE, GIVE RISE TO VARYING DEGREES OF UNPLEASANT EFFECTS.

They are rare and may consist of:

- nausea, vomiting,
- diarrhea,
- malaise with a drop in blood pressure, which may be accompanied by loss of consciousness,
- convulsions,allergic type reactions (anaphylactic shock, urticaria or angioedema, skin rash),
- thromboembolic symptoms (formation of blood clots) liable to occur in any part of the body.

REPORT ANY UNDESIRABLE OR UNPLEASANT EFFECT NOT MENTIONED IN THIS LEAFLET TO YOUR DOCTOR OR PHARMACIST.

STORAGE

DO NOT EXCEED THE EXPIRY DATE INDICATED ON THE OUTER PACKAGING.

Special storage precautions

Do not store above 25° C.

DATE OF LEAFLET REVISION

June 2005.