1.3.2 PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

RUBINEX solution for injection

Tranexamic acid

Read all of this leaflet carefully before you start taking RUBINEX

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- RUBINEX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What RUBINEX is and what it is used for

2. What you need to know before you take RUBINEX

3. How to take RUBINEX

4. Possible side effects

5 How to store RUBINEX

6. Contents of the pack and other information

1. WHAT RUBINEX IS AND WHAT IT IS USED FOR

RUBINEX contains tranexamic acid which belongs to a group of medicines called antihemorrhagics; antifibrinolytics.

RUBINEX is used in the treatment of

1. Hyphema (blood between the cornea and the iris of the eye) and patients with established coagulopathies (bleeding disorder) who are undergoing minor surgery
2. Hereditary angioedema (rapid swelling of the area beneath the skin or mucosa)

3. Menorrhagia (heavy periods in women)
4. Management of dental extraction in haemophiliacs (A disorder in which blood doesn't clot normally)

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RUBINEX

You should not receive RUBINEX if you:

- are allergic to tranexamic acid or any of the other ingredients of RUBINEX (listed in section 6)
- have (or ever have had) a disease that leads to blood clots
- have massive haemorrhage in the upper urinary tract
- have colour vision disorder
- impaired liver function
- suffer from thrombophlebitis (blood clot that blocks one or more veins, usually in the legs) and subarachnoid bleeding

If you think any of these apply to you, or if you are in any doubt at all, tell your doctor before taking RUBINEX.

Warnings and precautions

Tell your doctor if any of these apply to you to help him or her decide if RUBINEX is suitable for you:

- If you have blood in your urine, it may lead to urinary tract obstruction.
- If you have had convulsions, RUBINEX should not be administered. Your doctor must use the minimal dose possible to avoid convulsions following treatment with RUBINEX.
- If you are pregnant or breast feeding

- If you have kidney failure or impairment. Your doctor will adjust the dose accordingly.
- If you are taking oral contraceptives as potential for thrombus formation is increased.
- If you are on a long-term treatment with RUBINEX, attention should be paid to possible disturbances of colour vision and if necessary the treatment should be discontinued. With continuous long-term use of tranexamic acid regular ophthalmologic examinations (eye examinations including visual acuity, colour vision, fundus, visual field etc.) are indicated.

Other medicines and RUBINEX

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

You should specifically tell your doctor if you take:

- other medicines that help blood to clot called antifibrinolytic medicines
- medicines that prevent blood clotting, called thrombolytic medicines
- oral contraceptives

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking RUBINEX

Tranexamic acid is excreted in human milk. Therefore, the use of RUBINEX during breast-feeding is not recommended.

Driving and using machines

If you experience disturbances in vision or dizziness, you should not drive or operate any machines.

3. HOW RUBINEX SOLUTION FOR INJECTION IS GIVEN

RUBINEX is given by slow intravenous infusion/injection. Administration by injection is usually changed to oral administration after a few days.

RUBINEX is given as follows for each of the indications

Traumatic hyphaema:

1,0 to 1,5 g every 8 hours for six to seven days.

Patients with established coagulopathies undergoing minor surgery:

Conization of the cervix: 1,0 to 1,5 g every 8 to 12 hours for 12 days post-operatively.

Dental operations/extractions:

Factor VIII and Factor IX should be given as well as RUBINEX. After the operation, 25 mg/kg of RUBINEX is given 3 to 4 times a day for 6 to 8 days.

Hereditary angioedema:

Some patients are aware of the onset of illness; a suitable treatment for these patients is 1,0 - 1,5 g two to three times daily for some days. Other patients are treated continually at this dosage.

Menorrhagia:

RUBINEX solution for injection is administered intravenously by slow injection over a period of at least five minutes.

Method of administration

RUBINEX should only be administered slowly into a vein. RUBINEX must not be injected into a muscle.

4. POSSIBLE SIDE EFFECTS

RUBINEX can have side effects.

Not all side effects reported for RUBINEX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RUBINEX, please consult your health care provider for advice.

Side effects reported with RUBINEX are:

If you experience any of the following side effects after you have been given RUBINEX, tell your doctor immediately. If you are not in hospital, you MUST GO straight away. These side effects are less frequent but serious.

- Severe allergic reaction which may include a red and lumpy skin rash, difficulty breathing, swelling of face, mouth, lips or eyelids, unexplained high temperature (fever) and feeling faint. If the swelling affects your throat and makes breathing and swallowing difficult, go to hospital straight away.
- Symptoms of a blood clot which may include swelling or pain in your legs or chest, headache, weakness of the face and limbs on one side of the body.

Other side effects which may occur:

Frequent:

- nausea
- vomiting
- diarrhoea

Less Frequent:

- rash

Frequency unknown:

- malaise with hypotension (low blood pressure), especially if the injection is given too quickly
- convulsions
- vision disturbances, including impaired colour vision

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of RUBINEX

5. HOW TO STORE RUBINEX

Store all medicines out of reach of children.

Store at or below 25 °C. Do not freeze.

The solution for injection is for single use only. Unused solution for injection must be discarded.

Store in the original package.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What RUBINEX **contains**

The active substance of RUBINEX is tranexamic acid

The other ingredients are water for injection

What RUBINEX looks like and contents of the pack

Clear colourless solution for Injection packed in 5 ml fiolax clear glass ampoule made of USP Type I glass having white OPC dot with green & yellow band.

The primary packs are then packed in carton along with leaflet.

Holder of Certificate of Registration

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