

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

S4

### TRANEXAMIC INJECTION PHARMA-Q solution for injection

Tranexamic acid

Sugar free

**Read all of this leaflet carefully before you are given TRANEXAMIC INJECTION PHARMA-Q**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

#### What is in this leaflet

1. What TRANEXAMIC INJECTION PHARMA-Q is and what it is used for
2. What you need to know before you use TRANEXAMIC INJECTION PHARMA-Q
3. How to use TRANEXAMIC INJECTION PHARMA-Q
4. Possible side effects
5. How to store TRANEXAMIC INJECTION PHARMA-Q
6. Contents of the pack and other information

#### **1. What TRANEXAMIC INJECTION PHARMA-Q is and what it is used for**

TRANEXAMIC INJECTION PHARMA-Q contains tranexamic acid which belongs to the class of medicines called antifibrinolytics. TRANEXAMIC INJECTION PHARMA-Q is used to prevent or reduce bleeding in certain conditions, minor

surgery such as dental surgery in people with hereditary blood clotting disorders, and bleeding inside the eye.

## **2. What you need to know before you are given TRANEXAMIC INJECTION PHARMA-Q**

**TRANEXAMIC INJECTION PHARMA-Q should not be administered to you:**

- If you are hypersensitive (allergic) to tranexamic acid or any of the other ingredients of TRANEXAMIC INJECTION PHARMA-Q (listed in section 6).
- If you have currently a disease leading to blood clots
- If you have a condition called 'consumption coagulopathy' where blood in the whole body starts to clot
- If you have kidney problems
- If you have liver problems
- If you have a history of convulsions

Due to the risk of cerebral oedema and convulsions, intrathecal and intraventricular injection and intracerebral application are not recommended.

If you think any of these apply to you, or if you are in any doubt at all, tell your doctor before TRANEXAMIC INJECTION PHARMA-Q is given to you.

### **Warnings and precautions**

Tell your doctor or health care provider before being given the injection:

- If you have had blood in your urine, it may lead to urinary tract obstruction.
- If you have a risk of having blood clots.
- If you have excessive clotting or bleeding throughout your body (disseminated intravascular coagulation), TRANEXAMIC INJECTION PHARMA-Q may not be right for you, except if you have acute severe bleeding and blood test have

shown the process that inhibits blood clotting called fibrinolysis is activated.

- If you have had convulsions, TRANEXAMIC INJECTION PHARMA-Q should not be administered. Your doctor must use the minimal dose possible to avoid convulsions following treatment with TRANEXAMIC INJECTION PHARMA-Q.
- If you are on a long-term treatment with TRANEXAMIC INJECTION PHARMA-Q, 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 INJECTION PHARMA-Q, regular ophthalmologic examinations (eye examinations including visual acuity, colour vision, fundus, visual field etc.) are indicated. With pathological ophthalmic changes, particularly with diseases of the retina, your doctor must take a decision after consulting a specialist on the necessity for the long-term use of TRANEXAMIC INJECTION PHARMA-Q in your case.

### **Other medicines and TRANEXAMIC INJECTION PHARMA-Q**

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

You should specifically tell them if you take:

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

### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Women of childbearing potential have to use effective contraception during treatment.

Tranexamic acid is excreted in human milk. Therefore, the use of TRANEXAMIC INJECTION PHARMA-Q during breastfeeding is not recommended.

### **Driving and using machines**

It is not always possible to predict to what extent TRANEXAMIC INJECTION PHARMA-Q may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TRANEXAMIC INJECTION PHARMA-Q affects them, as it may cause dizziness or visual disturbances.

### **3. How to use TRANEXAMIC INJECTION PHARMA-Q**

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself TRANEXAMIC INJECTION PHARMA-Q.

It will be given to you by a person who is qualified to do so.

TRANEXAMIC INJECTION PHARMA-Q will be given to you by slow injection or infusion into a vein.

TRANEXAMIC INJECTION PHARMA-Q must not be injected into a muscle.

Your doctor will decide the correct dose for you and how long you should receive it.

If you have the impression that the effect of TRANEXAMIC INJECTION PHARMA-Q is too strong or too weak, tell your doctor or pharmacist.

**If you receive more TRANEXAMIC INJECTION PHARMA-Q than you should**

Since a health care provider will administer TRANEXAMIC INJECTION PHARMA-Q, he/ she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

**If you missed a dose of TRANEXAMIC INJECTION PHARMA-Q**

Since a health care provider will administer TRANEXAMIC INJECTION PHARMA-Q, it is unlikely that the dose will be missed.

**Possible side effects**

TRANEXAMIC INJECTION PHARMA-Q can have side effects.

Not all side effects reported for TRANEXAMIC INJECTION PHARMA-Q are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using TRANEXAMIC INJECTION PHARMA-Q, please consult your health care provider for advice.

If any of the following happens, stop using TRANEXAMIC INJECTION PHARMA-Q and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to TRANEXAMIC INJECTION PHARMA-Q. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

*Frequent*

- nausea,
- vomiting,
- diarrhoea.

*Less frequent*

- skin rash.

*Frequency unknown*

- dizziness,
- malaise with hypotension (low blood pressure), with or without loss of consciousness, especially if the injection is given too quickly,
- blood clots,
- convulsions (fits),
- vision disturbances including impaired colour vision,
- allergic reactions.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions & Quality Problem 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 TRANEXAMIC INJECTION PHARMA-Q.

#### **4. How to store TRANEXAMIC INJECTION PHARMA-Q**

Store all medicines out of reach of children.

- Store at or below 25 °C
- Do not freeze
- Keep the container in the outer carton
- TRANEXAMIC INJECTION PHARMA-Q is for single use only
- Do not use after the expiry date stated on the label/ carton
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

#### **5. Contents of the pack and other information**

##### **What TRANEXAMIC INJECTION PHARMA-Q contains**

- The active substance is tranexamic acid. Each 10 ml solution contains 1 000 mg tranexamic acid (100 mg/ml)
- The other ingredient is: Water for injection.

##### **What TRANEXAMIC INJECTION PHARMA-Q looks like and contents of the pack**

TRANEXAMIC INJECTION PHARMA-Q is a clear, colourless solution practically free from particles filled in clear glass ampoules.

10 ml in 10 ml clear glass ampoule with blue bands and white OPC mark packed in a PVC transparent rondo tray in a single carton.

10 ml in 10 ml flint USP Type-I glass vials with 20 mm rubber stoppers and 20 mm white aluminium flip-off seal and packed in a single carton.

**Holder of Certificate of Registration**

Pharma-Q Holdings (Pty) Ltd

50 Commando Road,

Industria West

Johannesburg

2093

**This leaflet was last revised in**

The date on the registration certificate of the medicine.

**Registration number**

540223

**Access to the corresponding Professional Information**

To follow