

PACKAGE LEAFLET: INFORMATION FOR THE USER

TIROPREST* 12.5 mg/ 50 ml vials
containing concentrate for solution for IV infusion

For intravenous use.

- **Active substance:** Each mL contains tirofiban hydrochloride monohydrate equivalent to 0.25 mg tirofiban
- **Excipient(s):** Citric acid, sodium citrate dihydrate and sodium chloride.

Read all of this LEAFLET carefully before you start taking this medicine, as it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *While taking this medicine, tell your doctor that you are using this medicine, when you go to a hospital or visit a doctor.*
- *Strictly adhere to the instructions written in this leaflet. Do not ever use a **higher or lower** doses other than the dose prescribed to you.*

1. WHAT TIROPREST IS AND WHAT IT IS USED FOR?

TIROPREST is a member of the medicine group called platelet aggregation inhibitors (by preventing platelets from clumping)

TIROPREST is supplied as a sterile, colorless concentrate for solution for further dilution in 50 mL small glass bottles (vials).

TIROPREST is a medicine, which is required be prepared and administered only by your doctor.

A certain type of chest pain, known as unstable angina, may develop as a result of blood flow to the heart is decreased. Your doctor has prescribed TIROPREST for you to promote blood flow to the heart and prevent possible complications of this condition (e.g. heart attack).

TIROPREST is also used in patients who undergo to balloon type procedures to improve blood flow to the heart

TIROPREST works by blocking platelets which are found in blood and responsible for clotting (platelets are cells which are forming clumps during blood clotting). TIROPREST prevents platelets from sticking together to form blood clots by blocking a receptor (receiver) on platelets and in association with this, from leading to chest pain and heart attacks by reducing blood flow to the heart.

2. BEFORE YOU TAKE *TIROPREST*

DO NOT take TIROPREST if you;

- are allergic (hypersensitive) to the active substance (tirofiban) or any of the other ingredients of this medicine,
- are bleeding internally or have a history of bleeding internally within the last 30 days,
- have a history of intracranial (within the skull) bleeding in the brain, intracranial (within the skull) tumor, abnormal blood vessels (malformation) or aneurysm (enlargement (dilation) of a vein),
- have severe uncontrolled high blood pressure (malignant hypertension).
- have a low blood platelet count (thrombocytopenia) or problems with blood clotting.
- developed thrombocytopenia (a low platelet count) if you had received treatment with TIROPREST or another medicine in the same group of drugs previously.
- have a history of stroke within the last 30 days or any history of haemorrhagic (with bleeding) stroke,
- have been seriously injured or had a major operation within the last 6 weeks
- have severe liver disease,
- have inflammation of the tissue covering around your heart (pericarditis).

Take special care with TIROPREST if you had or have had;

- heart massage (cardiopulmonary resuscitation), a procedure to break up kidney stones or a biopsy within the last 2 weeks,
- been seriously injured or had a major operation within the last 3 months,
- an ulcer in the stomach or intestine (duodenum) within the last 3 months,
- a recent bleeding disorder (within the last 1 year) such as bleeding in the stomach or intestine (gastrointestinal), or blood in your urine or stool,
- recent spinal procedure or a procedure applied to the bottom of your spine (spinal/epidural procedures),
- a history or symptoms of splitting of the aorta (dissection) which is the main artery that leads from the heart,
- uncontrolled high blood pressure (hypertension)
- an inflammation of the lining around your heart (pericarditis)
- an inflammation of the blood vessels
- problems with the blood vessels in the retina of your eye
- treatment with medications that help to prevent or dissolve blood clots,
- kidney problems,
- a special intravenous line inserted under your collar bone within the last 24 hours,
- heart failure,
- very low blood pressure due to a failing heart (cardiogenic shock),
- a liver disorder,

- low blood count or anemia,

Please consult your doctor, if any of the above warnings applies to you, even if this has been the case in the past.

Using TIROPREST with food and drink:

TIROPREST may be administered on a full or empty stomach.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

TIROPREST should not be used during pregnancy unless its use is considered essential.

Consult your doctor or pharmacist immediately, if you notice that you are pregnant during your treatment.

Breast-feeding

Consult your doctor or pharmacist before taking this medicine.

If you are breast-feeding, please inform your doctor. Your doctor will tell you whether using this medicine is appropriate for you.

Driving and using machines

There is no data available for the impacts of TIROPREST on driving and using machines.

Important information about some of the ingredients of TIROPREST

This medicinal product contains less than 23 mg sodium per 1 mL dose; i.e. essentially 'sodium free'.

Using with other medicines

In general, TIROPREST can be used with other medicines. However, it is important to tell your doctor if you are taking other medicines including over the counter drugs, as some drugs may affect each other's action. It is especially important to tell your doctor if you are taking other medicines that help prevent your blood from clotting such as warfarin.

If you have currently been using or have recently used any prescription or over-the counter drugs, please inform your doctor or your pharmacist about these.

3. How to use TIROPREST?**Instructions for appropriate use and dosing/ administration intervals:**

You have been given or planned to be given TIROPREST by a healthcare professional. Your doctor will decide on the dose of your medicine, depending on your condition and your weight.

Route and method of administration:

TIROPREST will be given to you as a slow injection (administration into a vein)

Different age groups:**Use in children:**

Safety and effectiveness in children have not been established.

Use in elderly:

No dosage adjustment is necessary for the elderly.

Special conditions for use:**Kidney failure:**

If you have severe kidney failure, tell your doctor. Your doctor will reduce your TIROPREST dose.

If you have the impression that the effect of TIROPREST is too strong or weak, talk to your doctor or pharmacist.

If you use more TIROPREST than you should

Dosing schedule will be adjusted by your doctor according to your condition and response to the therapy. However, if you think that you were given too much dose of TIROPREST, contact with your doctor or another healthcare professional.

If you have taken more TIROPREST than you should, talk to a doctor or pharmacist.

If you forget to take TIROPREST:

Dosing schedule will be adjusted by your doctor according to your condition and response to the therapy.

Do not take a double dose to make up for a forgotten dose.

Possible reactions that may occur when treatment with TIROPREST is discontinued:

Do not stop your treatment without consulting your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, side effects may occur in individuals who are sensitive to any of the other ingredients of TIROPREST.

Stop taking TIROPREST and tell your doctor IMMEDIATELY or go to the nearest hospital casualty department, if any of the following applies to you:

- Allergic reactions

These side effects are all very serious. If you have any of these, that means you have a severe allergy to TIROPREST. You may require emergency medical intervention or hospitalization. All these very serious side effects are considerably rare.

Inform your doctor immediately or go to the nearest hospital casualty department, if you notice any of the following:

- Fever, nausea
- Bleeding

These are all serious side effects. Emergency medical intervention may be required.

Tell your doctor if you notice any of the following:

- Headache

These are mild side effects of TIROPREST.

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

5. How to store TIROPREST

Keep TIROPREST out of the reach and sight of children, and in its original package.

TIROPREST must be stored at a room temperature under 30°C. It must not be frozen and must be protected from light.

Use in accordance with the expiry date.

Do not use TIROPREST after the expiry date stated on the packaging.

Marketing authorization holder :

Effectus İlaç Limited Şirketi

Katip Çelebi Mah. Sıraselviler Cad. No:24 D:2 34433 Beyoğlu/İstanbul/TURKEY

Manufacturer :

İdol İlaç Dolum Sanayi Tic. A.Ş.

Davutpaşa Cad. Cebe Ali Bey Sok. No:20 Zeytinburnu/İstanbul/TURKEY

This package leaflet was approved on dd.mm.yyyy