Package leaflet: Information for the user

Tirofiban Eugia 0,05 mg/ml, oplossing voor infusie
tirofiban

Read all of this leaflet carefully before you start taking this medicine because 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, nurse or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1. What Tirofiban Eugia is and what it is used for
2. What you need to know before you use Tirofiban Eugia
3. How to use Tirofiban Eugia
4. Possible side effects
5. How to store Tirofiban Eugia
6. Contents of the pack and other information

1. What Tirofiban Eugia is and what it is used for

Tirofiban Eugia is used to help assist the blood flow to your heart and to help prevent chest pain and heart attacks. It works by preventing platelets, cells found in the blood, from forming blood clots. This medicine may also be used in patients whose heart vessels are dilated with a balloon (percutaneous coronary intervention or PCI). This is a procedure, possibly with implantation of a small tube (stent), to improve the blood flow to the heart.
Tirofiban Eugia is intended for use with aspirin and unfractionated heparin.

2. What you need to know before you are use Tirofiban Eugia

Do not use Tirofiban Eugia

- if you are allergic (hypersensitive) to tirofiban or any of the other ingredients of this medicine (listed in Section 6 “What Tirofiban Eugia contains”)
- if you are bleeding internally or have a history of bleeding internally within the last 30 days.
- if you have a history of bleeding in the brain, brain tumor or abnormal blood vessels in the brain.
- if you have severe uncontrolled high blood pressure (malignant hypertension).
- if you have a low blood platelet count (thrombocytopenia) or problems with blood clotting.
- if you developed thrombocytopenia if you had received treatment with Tirofiban Eugia or another medicine in the same group of drugs previously.
- if you have a history of stroke within the last 30 days or any history of stroke with bleeding.
- if you have been seriously injured or had a major operation within the last 6 weeks.
- if you have severe liver disease.

Your doctor will review your medical history to see if you are at an increased risk of any side effects associated with being given this medicine.

Warnings and precautions

Talk to your doctor before using Tirofiban Eugia, if you have or have had:

- any medical problems
- any allergies
- cardiopulmonary resuscitation (CPR), a biopsy, or a procedure to break up kidney stones 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 1 year) such as bleeding in the stomach or intestine, or blood in your urine or stool
- recent spinal procedure
- a history or symptoms of splitting of the aorta (aortic dissection)
- uncontrolled high blood pressure (hypertension)
- an inflammation of the lining around your heart (pericarditis)
- an inflammation of the blood vessels (vasculitis)
- problems with the blood vessels in the back of your eye (retina)
- 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

Other medicines and Tirofiban Eugia

In general, Tirofiban Eugia can be used with other medicines. Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription, 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.

Tirofiban Eugia with food and drink
Food and drink have no effect on this medicine.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Driving and using machines
Due to your disease state, you will not be able to drive or operate machinery while Tirofiban Eugia is being used

Tirofiban Eugia contain sodium.

Tirofiban Eugia solution for infusion contains approximately 921 mg of sodium per 250 ml bag. This is equivalent to 46% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Tirofiban Eugia

Tirofiban Eugia should be prescribed by a qualified doctor who is experienced in the management of heart attacks.
You have been given, or are about to be given, Tirofiban Eugia into a vein. Your doctor will decide on the appropriate dose, depending on your condition and your weight.

Use in Children
The use in children is not recommended.

If you use more Tirofiban Eugia than you should
Your dose of Tirofiban Eugia is carefully monitored and checked by your doctor and pharmacist.

The most frequently reported symptom of overdose is bleeding. If you notice bleeding, you should notify your health care professional immediately.

If you forget to use Tirofiban Eugia
Your doctor will decide when to administer the dose.

If you stop using Tirofiban Eugia
Your doctor will decide when treatment should be stopped. However, if you wish to stop your treatment earlier, you should discuss other options with your doctor.

If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most common side effect of treatment with Tirofiban Eugia is bleeding which could occur anywhere in the body. This can become serious and may, rarely, be fatal.

If side effects occur, they may need medical attention. While using Tirofiban Eugia, if you develop any of the following symptoms, you should contact your doctor immediately:
- signs of bleeding in the skull such as pain in the head, sensory impairments (visual or hearing), difficulties in speech, numbness or problems with movement or balance
- signs of internal bleeding such as coughing up blood or blood in your urine or stool
- signs of serious allergic reactions such as difficulties in breathing and dizziness

Below is a list of side effects that have occurred in some people following treatment with Tirofiban Eugia.The side effects are listed in decreasing order of frequency.

<u>Very common (may affect more than 1 in 10 people):</u>
Bleeding after surgery
Bleeding under the skin at the site of an injection, or into a muscle, causing swelling
Small red bruises on the skin
Invisible blood in urine or stool
Feeling sick

Headache

Common (may affect up to 1 in 10 people):
Blood in urine
Coughing up of blood
Nose bleeds
Bleeding in the gums and mouth
Bleeding from vessel puncture site
Reduction in red blood cells (reduced haematocrit and haemoglobin)
Decreases in platelet count below 90,000/mm3
Fever

Uncommon (may affect up to 1 in 100 people):
Bleeding in the stomach or intestines
Vomiting of blood
Decreases in platelet count below 50,000/mm^3

Not known (frequency cannot be estimated from the available data):
Bleeding in the skull
Haematoma in the spinal region
Bleeding in the abdomen of the internal organs
Accumulation of blood around the heart
Bleeding in the lung
Acute and/or severe decreases in platelet counts below <20,000/mm3
Severe allergic reactions with tightness of chest, hives or nettle rash, including reactions that cause difficulty in breathing and dizziness

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 directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tirofiban Eugia

Your physician and pharmacist will know how to store and dispose of this medicine.
Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bag after EXP. The expiry date refers to the last day of that month.
Store in the original package in order to protect from light.

After opening : the product should be used immediately

Do not use this medicine if you notice there are visible particles or discolouration of the solution before use.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Tirofiban Eugia contains

The active substance is tirofiban hydrochloride monohydrate.
1 ml of Tirofiban Eugia solution for infusion contains 56 micrograms of tirofiban hydrochloride monohydrate whih is equivalent to 50 micrograms of tirofiban.

The other ingredients are: Sodium chloride, sodium citrate, citric acid anhydrous, water for injection, hydrochloric acid concentrated (for pH adjustment) and sodium hydroxide (for pH adjustment).

What Tirofiban Eugia looks like and contents of the pack

Tirofiban Eugia is a clear, colourless solution available in 300 ml bags
Pack size: 1 or 3 bag with 250 ml solution for infusion.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Houder van de vergunning:
Eugia Pharma (Malta) Limited
Vault 14, Level 2,
Valletta Waterfront,
Floriana FRN 1914, Malta

Voor correspondentie en inlichtingen:
Aurobindo Pharma B.V.
Baarnsche Dijk 1
3741 LN Baarn

Fabrikanten
APL Swift Services (Malta) Ltd,
HF26, Hal Far Industrial Estate, Hal Far,
Birzebbugia, BBG 3000, Malta

Arrow Génériques
26 avenue Tony Garnier, Lyon,
69007, Frankrijk

In het register ingeschreven onder:
RVG 132381

This medicinal product is authorised in the Member States of the EEA under the following names:

France	**:**	TIROFIBAN ARROW 50 microgrammes/mL, solution pour perfusion
Italy	**:**	Tirofiban Aurobindo
Netherlands	**:**	Tirofiban Eugia 0,05 mg/ml, oplossing voor infusie
Portugal	**:**	Tirofibano Generis

Deze bijsluiter is voor het laatst goedgekeurd in februari 2025.

The following is intended for healthcare professionals only

This product is for hospital use only, by specialist physicians experienced in the management of acute coronary syndromes.

Tirofiban Eugia should be administered with unfractionated heparin and oral antiplatelet therapy, including acetylsalicylic acid (ASA).

Posology and method of administration

In patients who are managed with an early invasive strategy for Non-ST-Segment Elevation Acute Coronary Syndrome (NSTE-ACS) butnot planned to undergo angiography for at least 4 hours and up to 48 hours after diagnosis, Tirofiban Eugia is given intravenously at an initial infusion rate of 0.4 microgram/kg/min for 30 minutes. At the end of the initial infusion, Tirofiban Eugia should be continued at a maintenance infusion rate of 0.1 microgram/kg/min. Tirofiban Eugia should be given with unfractionated heparin (usually an intravenous bolus of 50-60 Units (U)/kg simultaneously with the start of Tirofiban Eugia therapy, then approx. 1000 U per hour, titrated on the basis of the activated partial thromboplastin time (APTT), which should be about twice the normal value) and oral antiplatelet therapy, including but not limited to ASA, unless contraindicated.

In NSTE-ACS patients planned to undergo PCI within the first 4 hours of diagnosis or in patients with acute myocardial infarction intended for primary PCI, Tirofiban Eugia should be administered utilizing an initial bolus of 25 microgram/kg given over a 3 minute period, followed by a continuous infusion at a rate of 0.15 microgram/kg/min for 12-24, and up to 48 hours. Tirofiban Eugia should be administered with unfractionated heparin (dosage as above) and oral antiplatelet therapy, including but not limited to ASA, unless contraindicated.

No dosage adjustment is necessary for the elderly.

Patients with severe kidney failure
In severe kidney failure (creatinine clearance < 30 ml/min) the dosage of Tirofiban Eugia should be reduced by 50%.

Paediatric population
The safety and efficacy of Tirofiban Eugia in children have not been established.
No data are available.

Start and duration of Tirofiban Eugia
In patients who are managed with an early invasive strategy for NSTE-ACS butnot planned to undergo angiography for at least 4 hours and up to 48 hours after diagnosis, the Tirofiban Eugia 0.4 microgram/kg/min loading dose regimen should be initiated upon diagnosis. The recommended duration of the maintenance infusion should be at least 48 hours. Infusion of Tirofiban Eugia and unfractionated heparin may be continued during coronary angiography and should be maintained for at least 12 hours and not more than 24 hours after angioplasty/atherectomy. Once a patient is clinically stable and no coronary intervention is planned by the treating physician, the infusion should be discontinued. The entire duration of treatment should not exceed 108 hours.

If the patient diagnosed with NSTE-ACS and managed with an invasive strategy undergoes angiography within 4 hours after the diagnosis, the Tirofiban Eugia 25 microgram/kg dose bolus regimen should be initiated at the start of PCI with the infusion continued for 12-24 hours and up to

48 hours. In patients with acute myocardial infarction intended for primary PCI, the bolus infusion regimen should be initiated as soon as possible after diagnosis.

Concurrent therapy (unfractionated heparin, oral antiplatelet therapy, including ASA)
Treatment with unfractionated heparin is initiated with an intravenous bolus of 50-60 U/kg and then continued with a maintenance infusion of 1000 units per hour. The heparin dosage is titrated to maintain an APTT of approximately twice the normal value.
Unless contraindicated, all patients should receive oral antiplatelet agents, including but not limited to ASA, before the start of Tirofiban Eugia. This medication should be continued at least for the duration of the infusion of Tirofiban Eugia. Most studies investigating the administration of Tirofiban Eugia as an adjunct to PCI have used ASA in combination with clopidogrel as oral antiplatelet therapy. The efficacy of the combination of Tirofiban Eugia with either prasugrel or ticagrelor has not been established in randomised controlled trials.

If angioplasty (PCI) is required, heparin should be stopped after PCI, and the sheaths should be withdrawn once coagulation has returned to normal, e.g. when the activated clotting time (ACT) is less than 180 seconds (usually 2-6 hours after discontinuation of heparin).

Incompatibilities

Incompatibility has been found with diazepam. Therefore, Tirofiban Eugia and diazepam should not be administered in the same intravenous line.

No incompatibilities have been found with Tirofiban Eugia and the following intravenous formulations: atropine sulfate, dobutamine, dopamine, epinephrine HCl, furosemide, heparin, lidocaine, midazolam HCl, morphine sulfate, nitroglycerin, potassium chloride, propranolol HCl, and famotidine injection.

Instructions for use

Check the expiry date.
Do not withdraw solution directly from the container with a syringe.

To Open: Tear foil overpouch (250 ml Solution for Infusion) at notch and remove inner container. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired

Directions for Use of Containers
Do not use unless solution is clear and seal is intact.

Do not add supplementary medication or withdraw solution directly from the bag with a syringe.
CAUTION: Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

Preparation for administration
ministration
1. Identify the infusion port.
2. Break off the tamper-evident cover from the infusion port. Membrane below cover is sterile – disinfection of the membrane is not necessary!
3. Close roller clamp. Insert the spike until the plastic collar of the port meets the shoulder of the

spike. Use a non-vented set or close the air inlet.
4. Hang the bag on the infusion stand. Press drip chamber to get fluid level. Prime infusion set. Connect and adjust flow rate.

Use according to the dosage table. The following table is provided as a guide to dosage adjustment by weight.

Patient Weight (kg)	**0.4 microgram/kg/min Loading Dose Regimen Most Patients**		**0.4 microgram/kg/min Loading Dose Regimen Severe Kidney Failure**		**25 microgram/kg Dose Bolus Regimen Most Patients**		**25 microgram/kg Dose Bolus Regimen Severe Kidney Failure**	
	30 min Loading Infusion Rate (ml/hr)	Maintenance Infusion Rate (ml/hr)	30 min Loading Infusion Rate (ml/hr)	Maintenance Infusion Rate (ml/hr)	Bolus (ml)	Maintenance Infusion Rate (ml/hr)	Bolus (ml)	Maintenance Infusion Rate (ml/hr)
30-37	16	4	8	2	17	6	8	3

	0.4 microgram/kg/min Loading Dose RegimenMost Patients		**0.4 microgram/kg/min Loading Dose Regimen Severe Kidney Failure**		**25 microgram/kg Dose Bolus RegimenMost Patients**		**25 microgram/kg Dose Bolus Regimen Severe Kidney Failure**	
38-45	20	5	10	3	21	7	10	4
46-54	24	6	12	3	25	9	13	5
55-62	28	7	14	4	29	11	15	5
63-70	32	8	16	4	33	12	17	6
71-79	36	9	18	5	38	14	19	7
80-87	40	10	20	5	42	15	21	8
88-95	44	11	22	6	46	16	23	8
96-104	48	12	24	6	50	18	25	9
105-112	52	13	26	7	54	20	27	10
113-120	56	14	28	7	58	21	29	10
121-128	60	15	30	8	62	22	31	11
129-137	64	16	32	8	67	24	33	12
138-145	68	17	34	9	71	25	35	13
146-153	72	18	36	9	75	27	37	13

- Where the solution and container permit, parenteral drugs should be inspected for visible particles ordiscolouration before use.
- Tirofiban Eugia should only be given intravenously and may be administered with unfractionated heparinthrough the same infusion tube.
- It is recommended that Tirofiban Eugia be administered with a calibrated infusion set using sterileequipment.
- Care should be taken to ensure that no prolongation of the infusion of the initial dose occurs and that miscalculation of the infusion rates for the maintenance dose

on the basis of the patient's weight is avoided.

Special precautions for storage

Do not use Tirofiban Eugia after the expiry date which is stated on the bag after <EXP>. The expiry date refers to the last day of that month.
Store in the original package in order to protect from light.

Nature and contents of container

Tirofiban Eugia is a clear, colourless solution available in 300 ml bags
Pack size: 1 or 3 bags with 250 ml solution for infusion.

Not all pack sizes may be marketed.

Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.