



Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

**Tirofiban 50 micrograms/ml solution for
infusion**

tirofiban (as hydrochloride monohydrate)

PL 56284/0050

Eugia (UK) Ltd

LAY SUMMARY

Tirofiban 50 micrograms/ml solution for infusion

tirofiban (as hydrochloride monohydrate)

This is a summary of the Public Assessment Report (PAR) for Tirofiban 50 micrograms/ml solution for infusion. It explains how this product was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use this product.

This product will be referred to as Tirofiban in this lay summary for ease of reading.

This application was approved under International Recognition procedure (IRP). The Reference Regulator (RR) was the EU/EEA , with the procedure number (PT/H/2584/001/DC). The procedure followed route A.

This application was approved under Regulation 51B of the Human Medicines Regulation 2012, as amended (previously Article 10.1 of Directive 2001/83/EC, as amended).

For practical information about using Tirofiban, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What is Tirofiban and what is it used for?

This product is a generic medicine. This means that this medicine is the same as, and considered interchangeable with, a reference medicine already authorised, called AGGRASTAT® (50 micrograms/ml) solution for infusion.

Tirofiban is used to help assist the blood flow to your heart and to help prevent chest pain and heart attacks.

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 is intended for use with aspirin and unfractionated heparin.

How does Tirofiban work?

Tirofiban works by preventing platelets, cells found in the blood, from forming blood clots.

How is Tirofiban used?

The pharmaceutical form of this medicine is a solution for infusion, and the route of administration is intravenously (into a vein).

Tirofiban should be prescribed by a qualified doctor who is experienced in the management of heart attacks.

The patient's doctor will decide on the appropriate dose, depending on the patient's condition and weight.

Use in Children

The use in children is not recommended.

For further information on how Tirofiban is used, refer to the PIL and Summary of Product

Characteristics (SmPC) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This medicine can only be obtained with a prescription.

Or (if being administered by a healthcare practitioner):

The patient should ask the administering healthcare practitioner if they have any questions concerning their medicine.

What benefits of Tirofiban have been shown in studies?

Tirofiban is a generic medicine that fulfils criteria meaning that no additional studies are required. Tirofiban has been considered a generic medicine of the reference medicine based on a comparison of their physical and chemical characteristics.

What are the possible side effects of Tirofiban?

For the full list of all side effects reported with this medicine, see Section 4 of the PIL or the SmPC available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at <https://yellowcard.mhra.gov.uk> or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

Why was Tirofiban approved?

MHRA decided that the benefits are greater than the risks and recommended that this medicine can be approved for use.

What measures are being taken to ensure the safe and effective use of Tirofiban?

As for all newly-authorised medicines, an Risk Management Plan (RMP) has been developed for Tirofiban. The RMP details the important risks of Tirofiban, how these risks can be minimised, any uncertainties about Tirofiban (missing information), and how more information will be obtained about the important risks and uncertainties.

The following safety concerns have been recognised for Tirofiban:

Summary of safety concerns	
Important Identified risks	Haemorrhages
	Thrombocytopenia
	Allergic reactions including anaphylactic reactions
	Combination with heparin, warfarin and thrombolytics
Important potential risks	None
Missing information	Children aged < 18 years
	Use in patients with severe hepatic impairment
	Combination of tirofiban with either prasugrel or ticagrelor
	Use in pregnant/lactating women

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Tirofiban are continuously monitored

and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

Other information about Tirofiban

A marketing authorisation was granted in the United Kingdom on 29 May 2025.

The full PAR for Tirofiban follows this summary.

This summary was last updated in June 2025.

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I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the application(s) for Tirofiban 50 micrograms/ml solution for infusion (PL 56284/0050) could be approved.

The product is approved for the following indications:

Tirofiban is indicated for the prevention of early myocardial infarction in adult patients presenting with acute coronary syndromes without ST elevation (NSTEMI-ACS) with the last episode of chest pain occurring within 12 hours and with ECG changes and/or elevated cardiac enzymes.

Patients most likely to benefit from Tirofiban treatment are those at high risk of developing myocardial infarction within the first 3-4 days after onset of acute angina symptoms including for instance those that are likely to undergo an early percutaneous coronary intervention (PCI).

Tirofiban is also indicated for the reduction of major cardiovascular events in patients with acute myocardial infarction (STEMI) intended for primary PCI (see sections 4.2 and 5.1).

Tirofiban is intended for use with acetylsalicylic acid (ASA) and unfractionated heparin.

The active substance is tirofiban (as hydrochloride monohydrate) which belongs to the pharmacotherapeutic group of blood and blood forming organs – antithrombotic agents – antithrombotic agents – Platelet aggregation inhibitors excl. heparin.

Mechanism of action

Tirofiban hydrochloride (tirofiban) is a non-peptidal antagonist of the GP IIb/IIIa receptor, an important platelet surface receptor involved in platelet aggregation. Tirofiban prevents fibrinogen from binding to the GP IIb/IIIa receptor, thus blocking platelet aggregation.

Tirofiban leads to inhibition of platelet function, evidenced by its ability to inhibit ex vivo ADP-induced platelet aggregation and to prolong bleeding time (BT). Platelet function returns to baseline within eight hours after discontinuation. The extent of this inhibition runs parallel to the tirofiban plasma concentration.

This application was approved under International Recognition procedure (IRP). The Reference Regulator (RR) was the Choose a reference regulator, with the procedure number (PT/H/2584/001/DC).

For the scientific discussion of the quality, non-clinical and clinical assessment conducted by the reference regulator, please refer to the public assessment report on the relevant competent authority's website.

This application was approved under Regulation 51B of the Human Medicines Regulation 2012, as amended (previously Article 10.1 of Directive 2001/83/EC, as amended).

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for this product at all sites responsible for the manufacture, assembly and batch release of this product.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

A marketing authorisation was granted on 29 May 2025.

II. PRODUCT INFORMATION

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The SmPC is in line with current guidelines and is satisfactory.

PATIENT INFORMATION LEAFLET (PIL)

The PIL is in line with current guidelines and is satisfactory.

LABEL

The labelling is in line with current guidelines and is satisfactory.

III. QUALITY ASPECTS

MHRA considered that the quality data submitted for this application is satisfactory.

The grant of a marketing authorisation was recommended.

IV. NON-CLINICAL ASPECTS

MHRA considered that the non-clinical data submitted for this application is satisfactory.

The grant of a marketing authorisation was recommended.

V. CLINICAL ASPECTS

MHRA considered that the clinical data submitted for this application is satisfactory.

The grant of a marketing authorisation was recommended.

VI. RISK MANAGEMENT PLAN (RMP)

The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

VII. USER CONSULTATION

A full colour mock-up of the Patient Information Leaflet (PIL) was provided with the application in accordance with legal requirements, including user consultation.

VIII. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The benefit/risk balance is, therefore, considered to be positive.

The Summaries of Product Characteristics (SmPCs), Patient Information Leaflet (PIL) and labelling are satisfactory.

In accordance with legal requirements, the current approved UK versions of the SmPCs and PIL for these products are available on the MHRA website.

IX. TABLE OF CONTENT OF THE PAR UPDATE

Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations, where significant changes are made, are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPCs and/or PIL available on the MHRA website.

Application type	Scope	Product information affected	Date of grant	Outcome	Assessment report attached Y/N