LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Ticagrelor Intas (ticagrelor)

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Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

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ticagrelor

Film-coated tablet, 60 mg, 90 mg

This is a summary of the public assessment report (PAR) for Ticagrelor Intas. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Ticagrelor Intas and what is it used for?
The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Brilique.

The product is used in combination with acetylsalicylic acid (another antiplatelet agent) in adult patients that have had a heart attack or unstable angina (angina or chest pain that is not well controlled). It reduces the chances of having another heart attack, stroke or dying from a disease related to the heart or blood vessels.

How does Ticagrelor Intas work?
The product affects cells called 'platelets' (also called thrombocytes). These very small blood cells help stop bleeding by clumping together to plug tiny holes in blood vessels that are cut or damaged. However, platelets can also form clots inside diseased blood vessels in the heart and brain. The product helps stop the clumping of platelets. This reduces the chance of a blood clot forming that can reduce blood flow.

How is Ticagrelor Intas used?
The pharmaceutical form is film-coated tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Ticagrelor Intas have been shown in studies?
Because the product is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Brilique 90 mg film-coated tablets. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Ticagrelor Intas?
Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Ticagrelor Intas approved?
It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Brilique, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Ticagrelor Intas?
A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Ticagrelor Intas
The full PAR for Ticagrelor Intas can be found on the following website: MRI - Home. For more information about treatment with Ticagrelor Intas please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-03.