

Summary Public Assessment Report

**Ticagrelor Reddy
(ticagrelor)**

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ticagrelor

Film-coated tablet, 60 mg, 90 mg

This is a summary of the public assessment report (PAR) for Ticagrelor Reddy. 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 Reddy 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, film-coated tablets.

The reference medicine for the product is Brilique, film-coated tablets.

The company has provided additional own data to demonstrate the safety and efficacy of the product regarding this difference from the reference medicine.

The product in combination with acetylsalicylic acid (another antiplatelet agent) is to be used in adults only. You have been given this medicine because you have had:

Ticagrelor Reddy 60 mg film-coated tablets:

- a heart attack, over a year ago.

Ticagrelor Reddy 90 mg film-coated tablets:

- a heart attack, or
- unstable angina (angina or chest pain that is not well controlled).

It reduces the chances of you having another heart attack, stroke or dying from a disease related to your heart or blood vessels.

How does Ticagrelor Reddy work?

Ticagrelor Reddy contains an active substance called ticagrelor. This belongs to a group of medicines called antiplatelet medicines.

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It reduces the chances of you having another heart attack, stroke or dying from a disease related to your heart or blood vessels.

How is Ticagrelor Reddy used?

The pharmaceutical form is film-coated tablets 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 Reddy 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, 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 Reddy?

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 Reddy 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 Reddy?

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 Reddy

The full PAR for Ticagrelor Reddy can be found on the following website:
<http://mri.medagencies.org/Human/>. For more information about treatment with Ticagrelor Reddy, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2024-02.