Summary Public Assessment Report

Generics

Ticagrelor Swyssi 60 mg film-coated tablets
Ticagrelor Swyssi 90 mg film-coated tablets

ticagrelor

SK/H/0295/001-002/DC
Applicant: Swyssi AG, Germany

Date: 12.04.2024

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Generics

Ticagrelor Swyssi 60 mg film-coated tablet
Ticagrelor Swyssi 90 mg film-coated tablet

ticagrleor, 60 mg and 90 mg, film-coated tablet

This is a summary of the public assessment report (PAR) for Ticagrelor Swyssi. It explains how Ticagrelor Swyssi 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 Ticagrelor Swyssi.

For practical information about using Ticagrelor Swyssi, patients should read the package leaflet or contact their doctor or pharmacist.

What is Ticagrelor Swyssi and what is it used for?

Ticagrelor Swyssi is a 'generic medicine'. This means that Ticagrelor Swyssi is similar to a 'reference medicine' already authorised in the European Union (EU) called Brilique.

Ticagrelor Swyssi is used in combination with acetylsalicylic acid (another antiplatelet agent) as prevention of atherothrombotic events in adult patients with:
- acute coronary syndromes (ACS) or
- a history of myocardial infarction (MI) and a high risk of developing an atherothrombotic event (see sections 4.2 and 5.1).

Ticagrelor Swyssi 60 mg can be used by adult patients who have had a heart attack, over a year ago. It reduces the chances of having another heart attack, stroke or dying from a disease related to patient's heart or blood vessels.

Ticagrelor Swyssi 90 mg can be used by adult patients who 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 patient's heart or blood vessels.

How does Ticagrelor Swyssi work?

Ticagrelor Swyssi 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. This can be very dangerous because:
- the clot can cut off the blood supply completely; this can cause a heart attack (myocardial infarction) or stroke, or
- the clot can partly block the blood vessels to the heart; this reduces the blood flow to

the heart and can cause chest pain which comes and goes (called ‘unstable angina’).

Ticagrelor Swyssi helps stop the clumping of platelets. This reduces the chance of a blood clot forming that can reduce blood flow.

How is Ticagrelor Swyssi used?

The pharmaceutical form of Ticagrelor Swyssi is film-coated tablet and the route of administration is oral use.

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

Ticagrelor Swyssi 60 mg film-coated tablet

- The usual dose is one tablet of 60 mg twice a day as long as it is indicated by the doctor.
- This medicine should be taken around the same time every day (for example, one tablet in the morning and one in the evening).

Ticagrelor Swyssi 90 mg film-coated tablet

- The starting dose is two tablets at the same time (loading dose of 180 mg). This dose will usually be given to the patient in the hospital.
- After this starting dose, the usual dose is one tablet of 90 mg twice a day for up to 12 months unless the doctor indicates differently.
- This medicine should be taken around the same time every day (for example, one tablet in the morning and one in the evening).

Ticagrelor Swyssi can be taken with other medicines for blood clotting.
The doctor will usually also tell the patient to take acetylsalicylic acid. This is a substance present in many medicines used to prevent blood clotting. The doctor will tell the patient how much to take (usually between 75-150 mg daily).

The medicine can only be obtained with a prescription.

What benefits of Ticagrelor Swyssi have been shown in studies?

Because Ticagrelor Swyssi is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Brilique. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Ticagrelor Swyssi?

Because Ticagrelor Swyssi is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

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

Why is Ticagrelor Swyssi approved?

It was concluded that, in accordance with EU requirements, Ticagrelor Swyssi has been shown to be comparable to reference medicine. Therefore, the SIDC decided that, as for reference medicine called Brilique, the benefits are greater than its risk and recommended that it can be approved for use.

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

A risk management plan has been developed to ensure that Ticagrelor Swyssi 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 for Ticagrelor Swyssi, 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 Swyssi

The marketing authorisation for Ticagrelor Swyssi was granted on 12.04.2024.

The full PAR for Ticagrelor Swyssi can be found on the website sukl.sk. For more information about treatment with Ticagrelor Swyssi, read the package leaflet (*link*) or contact your doctor or pharmacist.

This summary was last updated in 04-2024.