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Public Assessment Report

Scientific discussion

Ticagrelor ELC 60 mg film-coated tablets
Ticagrelor ELC 90 mg film-coated tablets
(ticagrelor)

LT/H/0223/001-002/DC

Date: 13/04/2026

This module reflects the scientific discussion for the approval of Ticagrelor ELC 60 mg and 90 mg film-coated tablets. The procedure was finalised at 21 January 2026. For information on changes after this date please refer to the module 'Update'.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have granted a marketing authorisation for *Ticagrelor 60 mg & 90 mg film-coated tablets.*

The product is indicated for the 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 when co-administered with acetylsalicylic acid (ASA).

A comprehensive description of the indications and posology is given in the SmPC.

This decentralised procedure concerns a generic application claiming essential similarity with the innovator product Brilique 60 mg & 90 mg film-coated tablets authorized by AstraZeneca AB, Sweden via centralized procedure (approved 2010-12-03 in EU, MA number EU/1/10/655/007-011 for 60 mg and EU/1/10/655/006 for 90 mg).

The concerned member state (CMS) involved in this procedure were DE, ES, FR, IT and NL.

The marketing authorisation has been granted pursuant to Article 10(1) of Directive 2001/83/EC.

II. QUALITY ASPECTS

II.1 Introduction

Ticagrelor 60 mg film-coated tablets is round, biconvex, pink film-coated tablets debossed with "60" on one side, plain on the other side. The tablet size is 8 mm.
Ticagrelor 90 mg film-coated tablets is round, biconvex, yellow film-coated tablets debossed with "90" on one side, plain on the other side. The tablet size is 9 mm.
The film-coated tablets are packed in PVC/PVDC/Al blisters.

II.2 Drug Substance

The drug substance ticagrelor is an established active substance which is described in the Ph. Eur. monograph for ticagrelor (04/2021:3087). The drug substance is a white or almost white to pale pink powder, practically insoluble in water, freely soluble in methanol, soluble in anhydrous ethanol, practically insoluble in heptane. Ticagrelor exhibits polymorphism. The manufacturer confirmed throughout analysis using different techniques that the drug substance is consistently produced in the same form.
Current EDQM certificate of suitability (CEP) has been provided for the drug substance clarifying that the drug substance can be controlled adequately by the respective monograph of Ph. Eur.

Manufacturing process
A CEP has been submitted; therefore, no details on the manufacturing process have been included.

Quality control of drug substance

The drug substance specification is considered adequate to control the quality of ticagrelor and meets the requirements of the monographs of the Ph. Eur.. Batch analytical data demonstrating compliance with this specification have been provided.

Stability of drug substance
The drug substance is stable Assessment thereof was part of granting the CEP and has been granted by the EDQM.

II.3 Medicinal Product

Pharmaceutical development
The medicinal product is established pharmaceutical form, and the development is adequately described in accordance with the relevant European guidelines. The choice of excipients is justified and their functions explained. Bioequivalence (BE) studies were performed with the 90 mg product versus the 90 mg reference product. The biobatch was manufactured according to the finalized composition and manufacturing process. Comparative *in vitro* dissolution testing has been successfully studied in support of the bioequivalence study. The pharmaceutical development of the product has been adequately performed.

Manufacturing process
. The manufacturing process has been validated on the exhibit and commercial scale batches according to relevant European/ICH guidelines.

Control of excipients
The excipients are well known and commonly used in the composition of the tablets. Dibasic calcium phosphate dihydrate, mannitol, hydroxypropylcellulose, croscarmellose sodium, magnesium stearate and purified water comply with the specifications of the respective Ph. Eur. monographs current edition. The specifications for Opadry coating material were established with reference to the supplier's internal specification. The information presented on the excipients is sufficient.

Quality control of drug product
The finished product specification is adequate to control the relevant parameters for the dosage form. Limits in the specification have been justified and are considered appropriate for adequate quality control of the product. Satisfactory validation data for the analytical methods have been provided. Batch analytical data from the proposed production site have been provided, demonstrating compliance with the specification.

Stability of drug product
Stability data of the final drug product at long-term (25 ± 2°C/65 ± 5% RH) and accelerated (40 ± 2°C/75 ± 5% RH) storage conditions have been provided. The conditions used in the stability studies are according to the ICH stability guideline.. Photostability studies were performed in accordance with ICH recommendations and showed that the product is not stable when directly exposed to light. On basis of the data submitted, a shelf life was granted of three years with the storage conditions "This medicinal product does not require any special storage conditions".

II.4 Discussion on chemical, pharmaceutical and biological aspects

Based on the submitted dossier, the member states consider that Ticagrelor 60 mg & 90 mg film-coated tablets have a proven chemical-pharmaceutical quality. Sufficient controls have been laid down for the drug substance and finished medicinal product.

III. NON-CLINICAL ASPECTS

III.1 Introduction

The Non-Clinical Overview of ticagrelor has been prepared considering that the Marketing Authorisation Application (MAA) for this medicinal product is submitted under Article 10.1 of Directive 2001/83/EC, as amended, and Ticagrelor ELC 60 mg/90 mg is a generic medicinal product (Reference product Brilique 90 mg film-coated tablets; AstraZeneca AB, Sweden). The reference medicinal product has been authorised within the EU for more than 10 years, with recognised efficacy and an acceptable level of safety. Therefore, the Applicant is not required to provide additional non-clinical studies. To support the Application, a literature overview on non-clinical data has been submitted. The literature search strategy is well explained in the Overview and is deemed acceptable.
The Applicant has provided detailed data on impurity profile. All impurities are within acceptable limits, hence no further toxicological assessment is necessary.
The preclinical safety data included in the proposed Summary of Product Characteristics (SmPC) aligns with the originator's SmPC.

III.2 Ecotoxicity/environmental risk assessment (ERA)

The applicant submitted ERA.
Also considering AstraZeneca's environmental risk summaries of ticagrelor it was concluded by the applicant that the risk of bioaccumulation of ticagrelor in aquatic organisms is low and use of the ticagrelor has been considered to result in insignificant environmental risk.
. It can be concluded that Ticagrelor 60mg and 90mg film coated tablets can be marketed without presenting any significant risks to the environment.

III.3 Discussion on the non-clinical aspects

This product is generic formulation of ticagrelor, which are available on the European market. A non-clinical overview on the pharmacology, pharmacokinetics and toxicology has been provided, which is based on up-to-date and adequate scientific literature. The overview justifies why there is no need to generate additional non-clinical pharmacology, pharmacokinetics and toxicology data. Therefore, the member states agreed that no further non-clinical studies are required.

IV. CLINICAL ASPECTS

IV.1 Introduction

Ticagrelor is a well-known active substance with established efficacy and tolerability. A clinical overview has been provided, which is based on scientific literature. The overview justifies why there is no need to generate additional clinical data. Therefore, the member states agreed that no further clinical studies are required.
For this generic application, the MAH has submitted one bioequivalence study, which is discussed below.

IV.2 Pharmacokinetics

Biowaiver
The results of study with 90 mg formulation can be extrapolated to other strength (Ticagrelor 60 mg) as all conditions for a biowaiver laid out in the Guideline on the Investigation of Bioequivalence CPMP/EWP/QWP/1401/98 Rev. 1/Corr* section 4.1.6 are fulfilled.

Bioequivalence studies
The Applicant has submitted a single bioequivalence study.

An open label, balanced, randomized, single-dose, two-treatment, two-sequence, two period, two-way crossover oral bioequivalence study of Ticagrelor tablets 90 mg and Brilique® (Ticagrelor) tablets 90 mg of AstraZeneca AB, Sweden, in healthy, adult, human subjects under fasting conditions.

The measured pharmacokinetic parameters of Ticagrelor are summarized below:

Pharmacokinetic Parameters (Units)	Arithmetic Mean ± SD (%CV) (N =34)	
	Reference Product (R)	Test Product (T)
C_{max} (ng/mL)	701.889 ± 212.3721 (30.26%)	737.422 ± 198.6433 (26.94%)
$^{\#}T_{max}$ (hr)	1.670 (1.00 - 4.50)	1.670 (1.00 - 4.00)
AUC_{0-t} (hr*ng/mL)	5116.862 ± 1952.2350 (38.15%)	5235.296 ± 1687.0992 (32.23%)
$AUC_{0-\infty}$(hr*ng/mL)	5205.917 ± 2036.0010 (39.11%)	5318.173 ± 1747.8050 (32.86%)
$t_{½}$ (hr)	8.110 ± 1.2589 (15.52%)	7.742 ± 1.0611 (13.70%)
λz (1/hr)	0.087± 0.0138 (15.80%)	0.091 ± 0.0128 (13.99%)
AUC_%Extrap_obs (%)	1.531 ± 0.8044 (52.54%)	1.423 ± 0.7482 (52.59%)

$^{\#}$For T_{max} median (min – max)

The statistical results for primary pharmacokinetic parameters of Ticagrelor are summarized below:

PK Parameters (Unit)	Geometric Least Square Means and Its Ratio (N = 34)			Intra subject %CV	90% Confidence Interval	Power (%)
	Test Product (T)	Reference Product (R)	(T/R) (%)			
C_{max} (ng/mL)	710.519	671.669	105.78	18.10	98.26% - 113.88%	99.92
AUC_{0-t}	4978.190	4826.475	103.14	10.66	98.73% - 107.75%	100.00

Conclusion on bioequivalence studies:
Based on the submitted bioequivalence study/ies The Test Product (T) (Ticagrelor Tablets 90 mg) is considered bioequivalent with Reference medicinal product (R) [Brilique® (Ticagrelor) Tablets 90 mg].

The results of study with 90 mg formulation can be extrapolated to other strengths 60 mg, according to conditions in Guideline on the Investigation of Bioequivalence CPMP/EWP/QWP/1401/98 Rev. 1/Corr*, section 4.1.6.

IV.3 Pharmacodynamics

No new data have been submitted. No data are required for this generic application.

IV.4 Clinical efficacy

To support the application, the Applicant has submitted as report bioequivalence study. Provided that bioequivalence with the originator product is demonstrated, additional data is not necessary.

IV.5 Clinical safety

To support the application, the applicant has submitted as report bioequivalence study:
- Both (test and reference) treatments were well tolerated.
- No serious adverse events were reported.

IV.6 Risk Management Plan

The MAH has submitted a risk management plan in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterize, prevent or minimize risks relating to Ticagrelor ELC 60 mg and 90 mg film-coated tablets.

Summary of safety concerns

Important identified risks	• Increased risk of bleeding
Important potential risks	• None
Missing information	• Long-term use in patients with prior ischaemic stroke

Pharmacovigilance plan
No other routine pharmacovigilance activities beyond adverse reactions reporting and signal detection.
Plans for post-authorisation efficacy studies
No such studies planned.

Risk minimisation measures
The Applicant states that the safety information in the proposed product information is aligned to the reference medicinal product.

Summary of activities in the risk management plan by medicinal product

Routine pharmacovigilance activities are considered sufficient for this generic medicinal product:

1. Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
2. Important advice on the medicine's packaging;
3. The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;

4. The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

IV.7 Discussion on the clinical aspects

From a clinical point of view, the Bioequivalence study has demonstrated a bioequivalence between the reference product (Brilique ® 90 mg film-coated tablets, AstraZeneca AB, Sweden) and the proposed medicinal product (Ticagrelor 90 mg,). There are no objections from clinical point of view.

V. USER CONSULTATION

The package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC.
The results show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

Ticagrelor 60 mg & 90 mg film-coated tablets have a proven chemical-pharmaceutical quality and are generic form of Brilique 60 mg & 90 mg film-coated tablets. Brilique is well-known medicinal product with established favourable efficacy and safety profile.

Bioequivalence has been shown to be in compliance with the requirements of European guidance documents.

The decentralised procedure was finalised with a positive outcome on 21 January 2026.

Summary Public Assessment Report

Generics

Ticagrelor ELC 60 mg film-coated tablets
Ticagrelor ELC 90 mg film-coated tablets
(ticagrelor)

LT/H/0223/001-002/DC

Date: 13/04/2026

Summary Public Assessment Report

Generics

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

ticagrelor

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

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

What is Ticagrelor ELC and what is it used for?

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

This medicine 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').

[Invented name] helps stop the clumping of platelets. This reduces the chance of a blood clot forming that can reduce blood flow.

How is Ticagrelor ELC used?

The pharmaceutical form of Ticagrelor ELC is film-coated tablets and the route of administration is oral.

You have been given **Ticagrelor ELC 60 mg** because you have had a heart attack, over a year ago.

- The usual dose is one tablet of 60 mg twice a day. Continue taking this medicine as long as your doctor tells you.
- Take this medicine around the same time every day (for example, one tablet in the morning and one in the evening).

You have been given **Ticagrelor ELC 90 mg** because you have had:
- a heart attack, or
- unstable angina (angina or chest pain that is not well controlled).

- The starting dose is two tablets at the same time (loading dose of 180 mg). This dose will usually be given to you 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 your doctor tells you differently.
- Take this medicine around the same time every day (for example, one tablet in the morning and one in the evening).

The medicine can only be obtained with a prescription.

What benefits of Ticagrelor ELC have been shown in studies?
Because Ticagrelor ELC 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 ELC?

Because Ticagrelor ELC 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 ELC approved?

It was concluded that, in accordance with EU requirements, Ticagrelor ELC has been shown to have comparable quality and to be bioequivalent/be comparable to reference medicine. Therefore, the State Medicines Control Agency of Lithuania 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 ELC?

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

The marketing authorisation for Ticagrelor ELC was granted on 10/03/2026.

The full PAR for Ticagrelor ELC can be found on the website https://mri-production.cts-mrp.eu/home?domain=h . For more information about treatment with Ticagrelor ELC, read the package leaflet (*link*) or contact your doctor or pharmacist.

This summary was last updated in April 2026.

Viešojo vertinimo protokolo apžvalga
Ticagrelor ELC 60 mg plėvele dengtos tabletės
Ticagrelor ELC 90 mg plėvele dengtos tabletės
tikagreloras

Trumpa kokybinės dalies apžvalga
Vaistiniai preparatai Ticagrelor ELC 60 mg plėvele dengtos tabletės ir Ticagrelor ELC 90 plėvele dengtos tabletės registruojamos decentralizuotos procedūros būdu pagal Direktyvos 2001/83/EB 10 str. 1 d. (generinis). Vaistinio preparato veiklioji medžiaga tikagreloras yra aprašytas Europos farmakopėjoje (Eur. Farm.). Tikagreloro gamintojas pateikė galiojantį veikliosios medžiagos atitikties Europos farmakopėjai sertifikatą (CEP). Gatavo produkto gamintojo veikliosios medžiagos tikagreloro specifikacija yra tinkamos kokybės ir atitinka ES gairių reikalavimus. Pateikti serijų analizės sertifikatai atitinka patvirtintos specifikacijos reikalavimus.
Ticagrelor ELC 60 mg plėvele dengtos tabletės yra apvalios, abipus išgaubtos, rožinės, plėvele dengtos tabletės, kurių vienoje pusėje įspausta „60“, kita pusė – lygi, o skersmuo – 7,9–8,4 mm.
Ticagrelor ELC 90 plėvele dengtos tabletės yra apvalios, abipus išgaubtos, geltonos, plėvele dengtos tabletės, kurių vienoje pusėje įspausta „90“, kita pusė – lygi, o skersmuo – 8,9–9,4 mm.
Gatavo produkto sudėtyje yra šių pagalbinių medžiagų: tabletės šerdyje: manitolio (E421), kalcio-vandenilio fosfato dihidrato, hidroksipropilceliuliozės, kroskarmeliozės natrio, magnio stearato; tabetės plėvelėje - hipromeliozės 2910 (E464), titano dioksido (E171), talko, makrogolio 400 (E1521), geltonojo geležies oksido (E172). Pagalbinių medžiagų pasirinkimas yra pagrįstas, jos yra plačiai naudojamos farmacinių preparatų gamyboje. Bioekvivalentiškumo tyrimai atlikti su referenciniu vaistiniu preparatu Brilique 90 mg plėvele dengtos tabletės. Gatavo produkto gamybos metodas yra standartinis ir validuotas. Validacijos tyrimų duomenys patvirtina, kad kiekvienas gamybos etapas yra kontroliuojamas ir atsikartojantis Gatavo produkto išleidimo ir tinkamumo laiko pabaigos specifikacijų kokybė atitinka ES gairių reikalavimus. Analizės procedūrų aprašymai pateikti, metodai validuoti. Serijų analizės sertifikatai atitinka specifikacijos reikalavimus. Gatavas produktas pakuojamas į PVC/PVDC ir aliuminio folijos lizdines plokšteles po 56 plėvele dengtas tabletes. Gatavo produkto stabilumo tyrimai atlikti pagal ES gairių reikalavimus. Remiantis stabilumo tyrimų duomenimis nustatytas 3 metų tinkamumo laikas. Šiam vaistiniam preparatui specialių laikymo sąlygų nereikia.

Trumpa ikiklinikinės ir klinikinės dalies apžvalga
Ticagrelor ELC yra receptiniai vaistai.
Ticagrelor ELC skiriama kartu su acetilsalicilo rūgštimi (ASR) aterotrombozės reiškinių profilaktikai suaugusiems pacientams:
- ištiktiems sergantiems ūminiu koronariniu sindromu (ŪKS) arba
- anksčiau patyrusiems miokardo infarktą (MI), jeigu yra didelė aterotrombozės reiškinio išsivystymo rizika.

Paraiška registruoti vaistinį preparatą pateikta pagal direktyvos 2001/83/EB 10 str. 1d. („generinis“). Pareiškėjas įrodė, kad vaistiniai preparatai Ticagrelor ELC 60 mg plėvele dengtos tabletės ir Ticagrelor ELC 90 plėvele dengtos tabletės yra iš esmės panašūs į referencinius vaistinius preparatus Brilique 60 mg ir 90 mg plėvele dengtos tabletės.
Šis vaistas veikia kraujo kūnelius, vadinamus “plokštelėmis“ (taip pat vadinamas trombocitais). Šie labai maži kraujo kūneliai padeda stabdyti kraujavimą, sulipdami vienas su kitu ir užkimšdami mažas skylutes įpjautose ar kitaip pažeistose kraujagyslėse.
Deja, kraujo plokštelės taip pat gali sudaryti krešulių pažeistų širdies ir smegenų kraujagyslių viduje. Tai gali būti labai pavojinga, kadangi:
- krešulys gali visai užkirsti kelią kraujo tėkmei – tuomet gali ištikti širdies priepuolis (miokardo infarktas) arba insultas;
- krešulys gali dalinai užkirsti kelią kraujo tėkmei į širdį ir pabloginti jos kraujotaką – tuomet gali prasidėti krūtinės skausmas, kuris atsiranda ir išnyksta (taip vadinama nestabilioji krūtinės angina).

Ticagrelor ELC padeda neleisti plokštelėms sulipti vienai su kita ir tokiu būdu trukdo susidaryti kraujo krešuliui, kuris gali pabloginti kraujotaką.

Tikagreloro farmakodinaminės, farmakokinetinės ir toksikologinės savybės yra gerai žinomos. Kadangi pateikta generinė paraiška, yra referuojama į referencinio vaistinio preparato tyrimų duomenis, todėl naujų ikiklinikinių tyrimų duomenų pareiškėjas nepateikė.
Ticagrelor ELC 60 mg plėvele dengtos tabletės ir Ticagrelor ELC 90 mg plėvele dengtos tabletės yra per burną vartojami vaistiniai preparatai, jų kiekybinė ir kokybinė sudėtis bei farmacinė forma tokios pat kaip referencinio vaistinio preparato Brilique 60 mg ir 90 mg plėvele dengtos tabletės. Pateiktas klinikinis tyrimas, įrodantis šių vaistinių preparatų biologinį ekvivalentiškumą. Referencinė ir pripažįstančios valstybės narės sutarė, kad Ticagrelor ELC veiksmingumo ir saugumo duomenys yra panašūs į Brilique.
Registruotojas turi veikiančią farmakologinio budrumo sistemą, kuri kartu su rizikos valdymo planu yra parengta kaip to reikalauja teisės aktai. Nepageidaujami reiškiniai yra nuolat analizuojami po vaistinio preparato registracijos.

Remiantis pateiktais kokybės, saugumo ir veiksmingumo duomenimis, decentralizuotoje procedūroje dalyvaujančios referencinė valstybė narė (Lietuva) ir pripažįstančios valstybės narės (Vokietija, Ispanija, Prancūzija, Italija, Nyderlandai) nutarė, kad vaistinius preparatus Ticagrelor ELC 60 mg plėvele dengtos tabletės ir Ticagrelor ELC 90 mg plėvele dengtos tabletės registruoti galima ir europinė fazė buvo sėkmingai baigta (210 dieną) 2026-01-21.
Lietuvoje vaistinis preparatas užregistruotas 2026-03-10.