Medicines Evaluation Board

Public Assessment Report
Scientific discussion

Sacubitril/Valsartan Devatis 24 mg/26 mg, 49 mg/51 mg and 97 mg/103 mg film-coated tablets
(sacubitril sodium and valsartan disodium)

NL/H/5948/001-003/DC

Date: 23 October 2026

This module reflects the scientific discussion for the approval of Sacubitril/Valsartan Devatis 24 mg/26 mg, 49 mg/51 mg and 97 mg/103 mg film-coated tablets. The procedure was finalised on 11 June 2025. For information on changes after this date, please refer to section 'steps taken after finalisation' at the end of this PAR.

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List of abbreviations

AE	Adverse Event
AI	Acceptable Intake
ANOVA	Analysis of Variance
BCS	Biopharmaceutics Classification System (-based biowaiver)
BE	Bioequivalence
CBG /MEB	College ter Beoordeling van Geneesmiddelen / The Medicines Evaluation Board
CHMP	Committee for Medicinal Products for Human Use
CMD(h)	Coordination group for Mutual recognition and Decentralised procedure for human medicinal products
CMS	Concerned Member State(s)
DCP	Decentralised Procedure
EDMF	European Drug Master File
EDQM	European Directorate for the Quality of Medicines
EEA	European Economic Area
EMA	European Medicines Agency
ERA	Environmental Risk Assessment
ERP	European Reference Product
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practice
ICH	International Conference of Harmonisation (of Technical Requirements for Pharmaceuticals for Human Use)
LALA	Locally applied, locally acting products
MAH	Marketing Authorisation Holder
PAR	Public Assessment Report
PD	Pharmacodynamics
Ph.Eur.	European Pharmacopoeia
PK	Pharmacokinetics
PL	Package Leaflet
PSURs	Periodic safety update reports
QC	Quality control
RH	Relative Humidity
RMP	Risk Management Plan
RMS	Reference Member State
SmPC	Summary of Product Characteristics
TSE	Transmissible Spongiform Encephalopathy
USP/NF	United States Pharmacopoeia/National Formulary

Note: *Not all abbreviations may apply for this PAR.*

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have granted a marketing authorisation for Sacubitril/Valsartan Devatis 24 mg/26 mg, 49 mg/51 mg and 97 mg/103 mg film-coated tablets, from Devatis GmbH.

The products are indicated for:
Adult heart failure
The product is indicated in adult patients for treatment of symptomatic chronic heart failure with reduced ejection fraction.

Paediatric heart failure
The product is indicated in children and adolescents aged one year or older for treatment of symptomatic chronic heart failure with left ventricular systolic dysfunction.

A comprehensive description of the up-to-date indications and posology is given in the SmPC.

II. EXECUTIVE SUMMARY

II.1. Rationale for the product

The marketing authorisation has been granted pursuant to Article 10(1) Generic medicinal product application of Directive 2001/83/EC, which concerns a generic application.

To demonstrate bioequivalence with the reference medicinal product, the MAH has submitted data on a bioequivalence study with the 97mg/103 mg strength, and a justification for a biowaiver for the additional 24 mg/26 mg and 49/51 mg strengths. See Section V. Clinical aspects.

In this decentralised procedure the reference medicinal product is Entresto, which has been authorised in the EEA via the centralised procedure EU/1/15/1058 by Novartis Europharm Limited since 19 November 2015.

This application has been assessed with The Netherlands as Reference Member State (RMS) and Austria, Denmark, Finland, Germany, Norway and Sweden as concerned Member States (CMS).

II.2. About the product

Pharmaco-therapeutic group (ATC Code): C09DX04
Dispensing status: Prescription Only

II.3. General comments on the application

N/A

II.4. General comments on compliance with GMP, GLP, GCP and agreed ethical principles

The RMS has been assured that acceptable standards of GMP are in place for these product types at all sites responsible for the manufacture and assembly of this product.

For manufacturing sites within the Community, the RMS has accepted copies of current manufacturer authorisations issued by inspection services of the competent authorities as certification that acceptable standards of GMP are in place at those sites.

For manufacturing sites outside the Community, the RMS has accepted copies of current GMP Certificates of satisfactory inspection summary reports, 'close-out letters' or 'exchange of information' issued by the inspection services of the competent authorities (or those countries with which the EEA has a Mutual Recognition Agreement for their own territories) as certification that acceptable standards of GMP are in place at those non-Community sites.

GMP active substance
Regarding the statement on GMP for the active substance a statement/declaration is provided from the manufacturer(s) responsible for manufacture of the medicinal product and batch release situated in the EU.

GCP
Based on the data and documents submitted, the RMS has been assured that the studies were conducted and reported in compliance with GCP: a GCP statement and audit certificate(s) were provided; monitoring report(s) and recent inspection(s) by competent authorities identified no concerns relevant to the study; and, where conducted outside the EU, compliance with the ethical requirements of EU legislation (Directive 2001/20/EC or Regulation EU No. 536/2014, as relevant) was confirmed.

III. QUALITY ASPECTS

III.1. Introduction

Sacubitril/Valsartan Devatis are film-coated tablets. The film-coated tablets of the different strengths can be distinguished by their colour, size, and debossing and are as follows:

Sacubitril/Valsartan Devatis 24 mg/26 mg is a violet-white, oblong film coated tablet of approximately 9 mm x 5 mm. Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril sodium and valsartan disodium).

Sacubitril/Valsartan Devatis 49 mg/51 mg is a pale yellow, oblong film coated tablet of approximately 11 mm x 6 mm. Each film-coated tablet contains 48.6 mg sacubitril and 51.4 mg valsartan (as sacubitril sodium and valsartan disodium).

Sacubitril/Valsartan Devatis 97 mg/103 mg is a light pink, oblong film coated tablet of approximately 15 mm x 7 mm. Each film-coated tablet contains 97.2 mg sacubitril and 102.8 mg valsartan (as sacubitril sodium and valsartan disodium).

The excipients are:
Tablet core – anhydrous silica colloidal, microcrystalline cellulose, hydroxypropylcellulose, crosscarmellose sodium, magnesium stearate and talc.
Film-coat – partly hydrolysed poly(vinyl alcohol), talc, titanium dioxide (E171), glycerol, sodium lauryl sulfate, iron oxide black (E172) (24 mg/26 mg and 97 mg/103 mg only), iron oxide red (E172), iron oxide yellow (E172) (49 mg/51 mg only).

The cores of the tablet strengths are dose proportional.

The film-coated tablets are packed in polyvinyl chloride/ polychlorotrifluoroethylene-aluminium (PVC/PCTFE-aluminium) blisters.

III.2. Active Substance

The structure of the active substances have been adequately proven and its physico-chemical properties are sufficiently described. The active substances are sacubitril sodium and valsartan disodium; both are established active substances that are not described in the European Pharmacopoeia (Eur.Ph.).

Sacubitril sodium is an almost white to yellow powder and is freely soluble in water. It has two chiral centres, can exist in four isomers and is manufactured as one form consistently. The active substance exhibits polymorphism and the crystal form B is used.

Valsartan disodium is an almost-white to yellow powder and deliquescent in nature. It is freely soluble in anhydrous ethanol and water; practically insoluble in methylene chloride. The active substance has one chiral centre. The substance has an amorphous form, and as supplier stability results support this, follow-up of polymorphism testing was not considered necessary in the valsartan specification.

Manufacturing process
The manufacture of the active substances has been adequately described. The used starting materials, solvents and reagents are considered acceptable. Adequate tests and acceptable specifications have been adopted for these.

Quality control of the active substance
Sacubitril sodium
The active substance specification includes relevant tests and the limits for impurities and degradation products have been justified in accordance with the applicable ICH Guidelines for impurities in new Drug Substances and in-house specifications. The analytical methods applied are suitably described and non-compendial methods have adequately been validated. The active substance specification is considered adequate to control the quality. Batch analytical data demonstrating compliance with this specification have been provided for two batches.

Valsartan disodium
The active substance specification includes relevant tests and the limits for impurities and degradation products have been justified in accordance with the applicable ICH Guidelines for impurities in new Drug Substances and in-house specifications. The analytical methods applied are suitably described and non-compendial methods have adequately been validated. The active substance specification is considered adequate to control the quality. Batch

analytical data demonstrating compliance with this specification have been provided for two batches.

Stability of the active substance
Stability data have been submitted for six (sacubitril) and three (valsartan) production scale batches of the active substances in accordance with the applicable European guidelines. Based on the data submitted, the re-test period for the active substances was confirmed for 48 months when stored under the stated conditions. This is acceptable.

III.3. Medicinal Product

Pharmaceutical development
The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines. The choice of the excipients is justified, and their functions explained.

A bioequivalence (BE) study was performed with the 97 mg/103 mg strength versus the respective reference product strength. The test batch used in the BE study was manufactured according to the finalised composition and manufacturing process at a representative scale. For the two additional strengths a biowaiver is claimed. Comparative dissolution testing at 3 pHs (0.1N HCl, pH 4.5 acetate buffer and pH 6.8 phosphate buffer) has been adequately studied in support of the BE study and biowaiver of the additional strengths. The pharmaceutical development of the product has been adequately performed.

Manufacturing process
The manufacturing process has been sufficiently described and critical steps identified. The manufacturing process has been validated according to relevant European/ICH guidelines.

Process validation data on the product have been presented for three pilot scale batches per strength in accordance with the relevant European guidelines.

The product is manufactured using conventional manufacturing techniques. Process validation for full-scale batches will be performed post authorisation.

Control of excipients
The excipients comply with Ph.Eur. requirements with additional control of functionality-related characteristics or in-house requirements (film-coating mixtures). These specifications are acceptable.

Quality control of the medicinal product
The medicinal product specifications are adequate to control the relevant parameters for the dosage form. The specification includes tests for description, identification, water content, dissolution, uniformity of dosage units, assay, degradation products and microbiological quality. The release and shelf-life tests and limits are identical for all test parameters. Limits in the specification have been justified and are considered appropriate for the adequate quality control of the product.

An adequate risk evaluation report on nitrosamines has been submitted. No risk for the presence of nitrosamines in the medicinal product was identified. This justifies the absence of any further testing for nitrosamine impurity in the active substance and medicinal product.

Satisfactory validation data for the non-compendial analytical methods have been provided. Batch analytical data for three pilot scaled batches per strength batches from the proposed production site have been provided, demonstrating compliance with the specification.

Stability of the medicinal product

Stability data on the product have been provided for three production scaled batches per strength stored at 25°C/ 60% RH (24 months) and 40°C/75% RH (6 months). The stability was tested in accordance with applicable European guidelines. Photostability studies were performed in accordance with ICH recommendations. The results showed that the product is stable when exposed to light. Based on the data submitted, a shelf life of three years was granted. The labelled storage conditions are: This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from moisture.

Specific measures concerning the prevention of the transmission of animal spongiform encephalopathies

There are no substances of ruminant animal origin present in the product nor have any been used in the manufacturing of this product, so a theoretical risk of transmitting TSE can be excluded.

III.4. Discussion on chemical, pharmaceutical and biological aspects

Based on the submitted dossier, the Member States consider that Sacubitril/Valsartan Devatis has a proven chemical-pharmaceutical quality. Sufficient controls have been laid down for the active substance and medicinal product.

IV. NON-CLINICAL ASPECTS

IV.1. Introduction

Pharmacodynamic, pharmacokinetic and toxicological properties of sacubitril and valsartan are well known. As sacubitril and valsartan are widely used, well-known active substances, the MAH has not provided additional studies and further studies are not required. The submitted overview based on literature is appropriate.

IV.2. Ecotoxicity/environmental risk assessment (ERA)

At the time of the approval of this application, before 1 September 2024, the revised ERA guideline (EMEA/CHMP/SWP/4447/00 Rev. 1- Corr.*) was not yet applicable. Then the conclusion for this medicinal product was: since Sacubitril Valsartan Devatis is intended for generic substitution, this will not lead to an increased exposure to the environment. An environmental risk assessment was therefore not deemed necessary.

IV.3. Discussion on the non-clinical aspects

This product is a generic formulation of Entresto which is available on the European market. Reference was made to the preclinical data obtained with the reference medicinal product. A non-clinical overview on the pharmacology, pharmacokinetics and toxicology has been provided, which was 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.

V. CLINICAL ASPECTS

V.1. Introduction

Sacubitril and valsartan are well-known active substances with established efficacy and tolerability. A clinical overview has been provided, which is based on scientific literature. The Member States agreed that no further clinical studies are required, besides the one bioequivalence study discussed below. Bioequivalence has been investigated in line with the EMA Guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1/Corr**).

V.2. Pharmacokinetics

To support the application, the MAH has submitted one bioequivalence study comparing the pharmacokinetic profiles of the test product Sacubitril/Valsartan Devatis 97 mg/103 mg film-coated tablet, Devatis GmbH, Germany and the reference medicinal product Entresto 97 mg/ 103 mg film-coated tablet, Novartis Europharm Limited, Ireland. A biowaiver was requested for the lower strengths 24 mg/26 mg and 49 mg/51 mg. The formula and manufacturing process of the bioequivalence batch was identical to the formula proposed for marketing.

Biowaiver

According to the EMA bioequivalence guideline, the following general requirements must be met where a waiver for additional strength is claimed:

a. the pharmaceutical products are manufactured by the same manufacturing process,
b. the qualitative composition of the different strengths is the same,
c. the composition of the strengths are quantitatively proportional, i.e. the ratio between the amount of each excipient to the amount of active substance(s) is the same for all strengths (for immediate release products coating components, capsule shell, colour agents and flavours are not required to follow this rule),
d. appropriate *in vitro* dissolution data should confirm the adequacy of waiving additional *in vivo* bioequivalence testing.

The dissolution tests at pH 1.2, 4.5 and 6.8 show for the various strengths of the medicinal product that more than 85% of the active substances are released within 15 minutes. Therefore, the profiles can be considered as similar. As the conditions for the biowaiver criteria are met, a biowaiver for the lower strengths has been granted.

Bioequivalence study, AZBE082118

Design

A single-dose, randomised, open label, two-treatment, three-period, three-sequence, crossover, balanced, semi replicate bioequivalence study was carried out under fasted conditions in 36 healthy male subjects, aged number 20 - 44 years. Each subject received a single dose (97 mg/103 mg) of one of the sacubitril/ valsartan formulations. The tablet was orally administered with 240 mL water after an overnight fasting period of at least 8 hours. There were three dosing periods, separated by a washout period of two days.

The plasma concentration time curve was used to assess the rate and extent of absorption. Blood samples were collected pre-dose and at 0.083 (for sacubitril analysis only), 0.17 (for sacubitril analysis only), 0.25, 0.5, 0.75, 1, 1.25, 1.5, 1.75, 2, 2.25, 2.5, 2.75, 3, 3.25 (for sacubitril analysis only), 3.5, 3.75 (for sacubitril analysis only), 4, 4.5, 5, 6, 7 (for sacubitril analysis only), 8, 12 (for valsartan analysis only), 16 (for valsartan analysis only), and 24 (for valsartan analysis only) hours after administration of the products.

The SmPC recommends administering the product orally. The film-coated tablet may be administered with or without food. The tablets must be swallowed with a glass of water. Splitting or crushing of the tablets is not recommended.

The design of the study was considered acceptable as according to the SmPC sacubitril/valsartan may be administered without reference to food intake. The bioequivalence study under fasting conditions is in accordance with CPMP/EWP/QWP/1401/98 Rev. 1/ Corr ** Note for Guidance on the investigation of bioavailability and bioequivalence.

Bioanalytical/statistical methods
The bioanalytical method has been adequately validated according to current guidelines (ICH M10) and is considered acceptable for analysis of the plasma samples. The methods used in this study for the pharmacokinetic calculations and statistical evaluation are considered acceptable.

Results
36 subjects enrolled for the study. One subject was discontinued during period II due to an adverse event (joint disorder). One subject withdrew consent for personal reasons during period II. One subject was excluded from analysis due to emesis twice within the T_{max} period, which is cause for exclusion according to protocol criteria. A total of 33 subjects were eligible for pharmacokinetic analysis.

Table 1. Pharmacokinetic parameters (non-transformed values; arithmetic mean ± SD, t_{max} (median, range)) of sacubitril, 97 mg under fasted conditions.

Treatment N=33	AUC_{0-t} (ng.h/mL)	$AUC_{0-\infty}$ (ng.h/mL)	C_{max} (ng/mL)	t_{max} (h)
Test	2986.8 ± 827.8	3039.3 ± 829.4	2797.9 ± 1057.4	0.75 (0.25 - 3.50)
Reference	2930.1 ± 802.7	2984.4 ± 801.9	3057.2 ± 1440.6	0.50 (0.25 - 3.25)
***Ratio (90% CI)**	1.02 (0.99 – 1.05)	-	0.95 (0.86 – 1.06)	-

$AUC_{0-\infty}$	Area under the plasma concentration-time curve from time zero to infinity
AUC_{0-t}	Area under the plasma concentration-time curve from time zero to t = 24 hours
C_{max}	Maximum plasma concentration
t_{max}	Time after administration when maximum plasma concentration occurs
CI	Confidence interval
*	Back-transformed from ln-transformed least-squares mean values

Table 2. Pharmacokinetic parameters (non-transformed values; arithmetic mean ± SD, t_{max} (median, range)) of valsartan, 103 mg under fasted conditions.

Treatment N=33	AUC_{0-t} (ng.h/mL)	$AUC_{0-\infty}$ (ng.h/mL)	C_{max} (ng/mL)	t_{max} (h)
Test	22794.8 ± 8101.6	23974.9 ± 8243.8	4588.4 ± 1480.7	1.50 (1.00 - 4.00)
Reference	20804.4 ± 8603.9	22016.4 ± 8827.7	4200.6 ± 1572.4	1.50 (0.75 - 4.00)
***Ratio (90% CI)**	1.08 (0.98 – 1.20)	-	1.08 (0.98 – 1.18)	-

$AUC_{0-\infty}$	Area under the plasma concentration-time curve from time zero to infinity
AUC_{0-t}	Area under the plasma concentration-time curve from time zero to the last measurable plasma concentration
C_{max}	Maximum plasma concentration
t_{max}	Time after administration when maximum plasma concentration occurs
CI	Confidence interval
*	Back-transformed from ln-transformed least-squares mean values

Conclusion on bioequivalence study:
The 90% confidence intervals calculated for AUC_{0-t}, and C_{max} are within the conventional bioequivalence acceptance range of 80% – 125%. Based on the submitted bioequivalence study Sacubitril/Valsartan Devatis 97 mg/103 mg is considered bioequivalent with Entresto 97 mg/103 mg under fasted conditions.

As a biowaiver has been granted, the results of study AZBE082118 with the 97 mg/103 mg formulation can be extrapolated to the lower strengths 24 mg/26 mg and 49 mg/51 mg, in accordance with the conditions in the Guideline on the Investigation of Bioequivalence CPMP/EWP/QWP/1401/98 Rev. 1/ Corr **.

V.3. Summary Pharmacovigilance system

The MAH has submitted a signed Summary of the MAH's and/or Proposed Future MAH's Pharmacovigilance System. Provided that the Pharmacovigilance System Master File fully complies with the legal requirements as set out in the Commission Implementing Regulation and as detailed in the GVP module, the RMS considers the Summary acceptable.

V.4. 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, characterise, prevent or minimise risks relating to Sacubitril/Valsartan Devatis. At the time of approval, the accepted version of the RMP was version 0.3 with data lock point date 7 April 2025.

Table 3. Summary table of safety concerns as approved in the RMP

Important identified risks	Hypotension Renal impairment Hyperkalaemia Angioedema Embryo-foetal toxicity/lethality
Important potential risks	Neonatal/infantile toxicity through exposure from breast milk Hepatotoxicity Cognitive impairment Statin drug-drug interaction Long-term effects on growth, bone growth and mineralisation in the paediatric population
Missing information	Long term use of LCZ696 (sacubitril/valsartan) in HF patients Use in Angiotensin-Converting Enzyme Inhibitor/ Angiotensin II Receptor Blocker (ACEI/ARB) naïve HF patients

The Member States agreed that routine pharmacovigilance activities and routine risk minimisation measures are sufficient for the risks and areas of missing information.

A specific structured questionnaire to obtain information on reported adverse drug reactions (dementia-related events, hepatotoxicity, angioedema and statin-related events) related to rivaroxaban administration is planned and will be implemented, in line with the routine pharmacovigilance activities of the reference medicinal product.

V.5. Discussion on the clinical aspects

For this authorisation, reference is made to the clinical studies and experience with the reference medicinal product Entresto. No new clinical studies were conducted. The MAH demonstrated through a bioequivalence study and biowaiver that the pharmacokinetic profile of the product is similar to the pharmacokinetic profile of this reference medicinal product. Risk management is adequately addressed. This generic medicinal product can be used instead of the reference medicinal product.

VI. USER CONSULTATION

The package leaflet (PL) 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 language used for the purpose of user testing the PL was English.

A user consultation with target patient groups on the package leaflet (PL) has been performed based on a bridging report making reference to Entresto, EU/1/15/1056/001-022, and Lenalidomide Devatis, NL/H/4989/001. The bridging report submitted by the MAH has been found acceptable; bridging is justified for both content (Entresto) and layout (Lenalidomide Devatis) of the leaflet.

VII. POST-APPROVAL COMMITMENTS (PAC's)

Post-approval commitments: not applicable.

VIII. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

Sacubitril/Valsartan Devatis 24 mg/26 mg, 49 mg/51 mg and 97 mg/103 mg film-coated tablets have a proven chemical-pharmaceutical quality and are generic forms of Entresto 97 mg/ 103 mg film-coated tablets. Entresto is a well-known medicinal product with an established favourable efficacy and safety profile.

Bioequivalence has been shown between the test and reference medicinal products, in line with the requirements of European guidance documents.

The Board followed the advice of the assessors.

There was no discussion in the CMD(h). Agreement between Member States was reached during a written procedure. The Member States, based on the data submitted, considered that bioequivalencey has been demonstrated for Sacubitril/Valsartan with the reference medicinal product, and have therefore granted a marketing authorisation. The decentralised procedure was finalised with a positive outcome on 11 June 2025.

IX. RECOMMENDATIONS AND CONDITIONS FOR MARKETING AUTHORISATION AND PRODUCT INFORMATION

IX.1. List of recommendations not falling under Article 21a/22 of Directive 2001/83/EC

N.A.

IX.2. List of conditions pursuant to Article 21a or specific obligations pursuant to Article 22 of Directive 2001/83/EC

N.A

STEPS TAKEN AFTER THE FINALISATION OF THE INITIAL PROCEDURE - SUMMARY

Procedure number	Scope	Product Information affected	Date of end of procedure	Approval/ non approval	Summary/ Justification for refuse
N.A.	N.A.	N.A.	N.A.	N.A.	N.A.