LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Sacubitril/Valsartan Reddy
(sacubitril sodium, valsartan disodium)

SE/H/2609/001-003/DC

This module reflects the scientific discussion for the approval of Sacubitril/Valsartan Reddy. The procedure was finalised at 2026-03-04. For information on changes after this date please refer to the module 'Steps taken after the finalisation of the initial procedure - Summary'.

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I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have agreed to grant a marketing authorisation for Sacubitril/Valsartan Reddy, 24 mg/26 mg, 49 mg/51mg, 97 mg/103 mg, Film-coated tablet.

The active substance is sacubitril, sacubitril sodium, valsartan disodium, valsartan. A comprehensive description of the indication and posology is given in the SmPC.

II. EXECUTIVE SUMMARY

II.1 About the product

Pharmacotherapeutic group: Agents acting on the renin-angiotensin system; angiotensin II receptor blockers (ARBs), other combinations, ATC code: C09DX04

Mechanism of action

Sacubitril/valsartan exhibits the mechanism of action of an angiotensin receptor neprilysin inhibitor by simultaneously inhibiting neprilysin (neutral endopeptidase; NEP) via LBQ657, the active metabolite of the prodrug sacubitril, and by blocking the angiotensin II type-1 (AT1) receptor via valsartan. The complementary cardiovascular benefits of sacubitril/valsartan in heart failure patients are attributed to the enhancement of peptides that are degraded by neprilysin, such as natriuretic peptides (NP), by LBQ657 and the simultaneous inhibition of the effects of angiotensin II by valsartan. NPs exert their effects by activating membrane-bound guanylyl cyclase-coupled receptors, resulting in increased concentrations of the second messenger cyclic guanosine monophosphate (cGMP), which could result in vasodilation, natriuresis and diuresis, increased glomerular filtration rate and renal blood flow, inhibition of renin and aldosterone release, reduction of sympathetic activity, and anti-hypertrophic and anti-fibrotic effects.

Valsartan inhibits detrimental cardiovascular and renal effects of angiotensin II by selectively blocking the AT1 receptor, and also inhibits angiotensin II-dependent aldosterone release. This prevents sustained activation of the renin-angiotensin-aldosterone system that would result in vasoconstriction, renal sodium and fluid retention, activation of cellular growth and proliferation, and subsequent maladaptive cardiovascular remodelling.

II.2 General comments on the submitted dossier

The application for Sacubitril/Valsartan Reddy, 24 mg/26 mg, 49 mg/51mg, 97 mg/103 mg, film-coated tablet, is a Generic Art. 10(1) application submitted according to Directive 2001/83/EC. The applicant applies through the Decentralised Procedure with Sweden acting as reference member state (RMS) and Germany and Romania as concerned member states (CMS).

The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is Entresto, 24 mg/26 mg, film-coated tablet authorised in the Union since 2015, with Novartis Europharm Limited as marketing authorisation holder.

The reference products used in the bioequivalence studies are Entresto, 24 mg/26 mg, film-coated tablet and Entresto, 97 mg/103 mg, film-coated tablet from Germany with Novartis Europharm Limited as marketing authorisation holder.

II.3 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, except for ALS Germany GmbH, for whom the certificate is not yet assessed by the Swedish medical agency inspectorate.

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 finished product and batch release situated in the EU.

GCP aspects
A statement on the application of appropriate GCP standards in the submitted studies has been provided. No issues regarding GCP have been identified. The clinical and the bioanalytical facilities were inspected by the UK authority (MHRA) in 2019 and by the FDA in 2022 and 2023 respectively, without any critical findings. No inspection of the submitted bioequivalence studies is needed.

III. SCIENTIFIC OVERVIEW AND DISCUSSION

III.1 Quality aspects

Drug substance
The structure of the drug substance has been adequately proven, and its physico-chemical properties are sufficiently described.

The manufacture of the drug substance has been adequately described, and satisfactory specifications have been provided for starting materials, reagents and solvents.

The drug substance specification includes relevant tests and the limits for impurities and degradation products have been justified. The analytical methods applied are suitably described and validated.

Stability studies confirm the retest period.

Drug Product
The medicinal product is formulated using excipients listed in section 6.1 in the Summary of Product Characteristics.

The manufacturing process has been sufficiently described and critical steps identified.

The tests and limits in the specification are considered appropriate to control the quality of the finished product in relation to its intended purpose.

Stability studies have been performed and data presented support the shelf life and special precautions for storage claimed in the Summary of Product Characteristics, sections 6.3 and 6.4.

III.2 Non-clinical aspects

Pharmacology/Pharmacokinetics/Toxicology
Pharmacodynamic, pharmacokinetic and toxicological properties of sacubitril and valsartan are well known. As sacubitril and valsartan is a widely used, well-known active substance, no further studies are required, nor does the applicant provide any. Overview based on literature review is, thus, appropriate.

Shortly, Sacubitril/Valsartan tablets is a fixed dose combination product indicated in adult patients for treatment of symptomatic chronic heart failure with reduced ejection fraction, and in children and adolescents aged one year or older for treatment of symptomatic chronic heart failure with left ventricular systolic dysfunction. The recommended starting dose of Sacubitril/Valsartan is one tablet of 49 mg/51 mg twice daily. The dose should be doubled at 2-4 weeks to the target dose of one tablet of 97 mg/103 mg twice daily. Sacubitril/valsartan exhibits the mechanism of action of an angiotensin receptor neprilysin inhibitor by simultaneously inhibiting neprilysin (neutral endopeptidase; NEP) via LBQ657, the active metabolite of the prodrug sacubitril, and by blocking the angiotensin II type-1 (AT1) receptor via valsartan.

Environmental Risk Assessment (ERA) – Art-10 ERA document

A so called 'Art-10 ERA' document (*i.e.*, a document that identifies a standard ERA from another product as a reference ERA) has been provided by the applicant in order to justify that the conclusions about environmental risk ("no risk") of a previous regulatory assessed reference ERA – identified as the reference ERA for Entresto, approved in 2015 - are also applicable for the present proposed product. No full data access was provided by the reference ERA owner but a summary of the ERAs for both APIs (Sacubitril and Valsartan) were provided. In the case of Sacubitril, the Entresto ERA used the active metabolite, LBQ657, as test item in the ecotoxicological studies. These summaries are listed below (as provided by the reference ERA owner):

Substance (INN/Invented Name): LBQ657 (active metabolite to the prodrug Sacubitril**)**			
CAS-number (if available): 149709-44-4			
PBT screening		Result	**Conclusion**
Bioaccumulation potential - log Kow or D	OECD TG107	Maximum 2.9 (for pH 2).	Potential PBT? No
PBT-assessment			
Parameter	**Result relevant for conclusion**		**Conclusion**
Bioaccumulation	log *D* or Kow	2.9	not B
	BCF	NA	not B
Persistence	DT50	23 d at 12 °C	not P
Toxicity	NOEC	≥ 10 mg/L	not T
PBT-statement :	The compound is not considered as PBT.		
Phase I			
Calculation	**Value**	**Unit**	**Conclusion**
PEC_{SW}, default	0.97	µg/L	> 0.01 threshold Yes
Other concerns (e.g.	NA	NA	No

chemical class)					
Phase II Physical-chemical properties and fate					
Study type	**Test protocol**	**Results**			**Remarks**
Adsorption-Desorption	OECD TG106	Sludge Koc 22.6 and 45.0 L/kg Soil Koc Non-sterilised soil: 367 L/kg Sterilised soil: 39.2 and 40.6 L/kg			2 sludge types 3 soil types
Ready Biodegradability Test	OECD TG301B	Not readily biodegradable			
Aerobic and Anaerobic Transformation in Aquatic Sediment systems	OECD TG308	DegT50, system = 11d and 11d DissT50, water = 6.0d and 6.5d % shifting to sediment: 36% and 56% at day 14, increasing thereafter			Values determined at 20°C
Phase IIa Effect studies					
Study type	**Test protocol**	**Endpoint**	**value**	**Unit**	**Remarks**
Algae, Growth Inhibition Test / *P. subcapitata*	OECD TG201	NOEC	≥ 100	mg/L	Growth rate
Daphnia sp. Reproduction Test	OECD TG211	NOEC	46	mg/L	Reproduction and growth
Fish, Early Life Stage Toxicity Test/ *P. Promelas*	OECD TG210	NOEC	≥ 10	mg/L	Survival and growth
Activated Sludge, Respiration Inhibition Test	OECD TG209	NOEC EC10	≥ 1000 756	mg/L	Respiration
Phase IIb Studies					
Sediment dwelling organism/ *C. riparius*	OECD TG218	NOEC	≥ 1867	mg/kg	Emergence and development, normalised to 10% O.C.

Substance (INN/Invented Name): Valsartan			
CAS-number (if available): 137862-53-4			
PBT screening		Result	**Conclusion**
Bioaccumulation potential - log Kow or D	OECD TG117	log D (pH 2.5) = 2.8 log D (pH 7.0) = 1.2*	Potential PBT? No
PBT-assessment			
Parameter	**Result relevant for conclusion**		**Conclusion**
Bioaccumulation	log *K*ow or D	log D (pH 2.5) = 2.8 log D (pH 7.0) = 1.2*	not B

	BCF	NA			not B
Persistence	DT50	DT50 total system 25.6–34.3 days DT50 sediment 5.5 – 7.5 days			not P
Toxicity	NOEC	CMR			T
PBT-statement :	Valsartan is considered to be not PBT, nor vPvB				
Phase I					
Calculation	**Value**	**Unit**			**Conclusion**
PEC_{SW}, default	1.028	µg/L			> 0.01 threshold Yes
Other concerns (e.g. chemical class)	NA	NA			No
Phase II Physical-chemical properties and fate					
Study type	**Test protocol**	**Results**			**Remarks**
Adsorption-Desorption Sludge 1 = Tilburg Sludge 2 = St Oendenrode Sludge 3 = 's-Hertogenbosch	OECD TG106	Koc, sludge 1 = 41 L/kgoc Koc, sludge 2 = 52 L/kgoc Koc, sludge 3 = 58 L/kgoc			3 sludge types No soil adsorption assessment.
Ready Biodegradability Test	OECD TG301	Not readily biodegradable			
Aerobic and Anaerobic Transformation in Aquatic Sediment systems Sediment 1 = sandy loam Sediment 2 = silt loam	OECD TG308	<u>*DT50*</u> Whole system: 16.1d / 12.0d Water: 13.6d / 9.4d Sediment: 3.5d / 2.6d <u>*Shifting to sediment*</u> (d14 and test end): 20% and 27% CO2 = 29 / 17 % NER = 45 / 50 % Transformation products >10% = Y, (at test end) TP1 = 0.2% / 3.2% TP5 = n.d. / 0.1%,			Values determined at 20°C
Phase IIa Effect studies					
Study type	**Test protocol**	**Endpoint**	**value**	**Unit**	**Remarks**
Algae, Growth Inhibition Test / *Raphidocelis subcapitata*	OECD TG201	NOEC	≥ 100	mg/L	Growth rate
Daphnia sp. Reproduction Test	OECD TG211	NOEC	5.6	mg/L	Reproduction and growth
Fish, Early Life Stage Toxicity Test/ *P. promelas*	OECD TG210	NOEC	≥ 10	mg/L	Survival and growth
Activated Sludge, Respiration Inhibition Test	OECD TG209	NOEC	≥ 750	mg/L	Respiration
Phase IIb Studies					

Sediment dwelling organism/ *C. riparius*	OECD TG218	NOEC	≥ 400	mg/kg	

- Same ionized species throughout the environmentally relevant pH range 5 to 9. Fraction of neutral form increases at lower pHs, up to around 90% neutral form at pH 2.5.

For both API, outcomes from a full Phase IIA dossier under the 2006 ERA-GL system plus sediment-dweller toxicity studies have been provided. Regarding the technical criteria of the 2024 ERA-GL, the applicant argues that:

- *Environmental exposure:* The maximum environmental exposure setting (based on Phase I default Fpen of 0.01) was used. As such, there are no relevant differences between he rERA and the present product conditions.
- *Secondary poisoning:* As the log D for both API was <3, no OECD TG305 fish study or secondary poisoning assessment is necessary.
- *Soil assessment trigger:* The sludge adsorption (Koc) was < 1000 L/kg for both API. As such, the level of PECsw was not relevant and no Phase IIB soil assessment is necessary.

Overall, the applicant concludes that the environmental risk conclusions of the refence ERA (from Entresto), are also applicable for the proposed product.

Based on the data provided by the Applicant, Sacubitril/Valsartan Reddy is not expected to pose a risk to the environment

III.3 Clinical aspects

Pharmacokinetics
To support the marketing authorisation application the applicant has conducted two bioequivalence studies comparing Sacubitril/Valsartan Reddy (Sacubitril/Valsartan) with the reference product Entresto.

Pharmacokinetic properties of the active substances
Absorption: Following oral administration, sacubitril/valsartan dissociates into valsartan and the prodrug sacubitril. Sacubitril is further metabolised to the active metabolite sacubitrilat (LBQ657). These reach peak plasma concentrations in 2 hours, 1 hour, and 2 hours, respectively. The oral absolute bioavailability of sacubitril and valsartan is estimated to be more than 60% and 23%, respectively.

Following twice daily dosing of sacubitril/valsartan, steady-state levels of sacubitril, LBQ657 and valsartan are reached in three days. At steady state, sacubitril and valsartan do not accumulate significantly, while LBQ657 accumulates 1.6-fold. Administration with food has no clinically significant impact on the systemic exposures of sacubitril, LBQ657 and valsartan. Sacubitril/valsartan can be administered with or without food.

Linearity: The pharmacokinetics of sacubitril, LBQ657 and valsartan were approximately linear over a sacubitril/valsartan dose range of 24 mg sacubitril/26 mg valsartan to 97 mg sacubitril/103 mg valsartan.

Elimination: Sacubitril, LBQ657 and valsartan are eliminated from plasma with a mean elimination half-life (T½) of approximately 1.43 hours, 11.48 hours, and 9.90 hours, respectively.

Study 63824 (24 mg/26 mg)

Methods

This was a two-treatment, four-period, two-sequence single-dose crossover, fully replicate bioequivalence study conducted in 48 healthy volunteers, comparing Sacubitril/Valsartan, 24 mg/26 mg, film-coated tablet with Entresto, 24 mg/26 mg, film-coated tablet under fasting conditions. Blood samples for concentration analysis were collected pre-dose and up to 48 hours post-dose. Plasma concentrations of sacubitril and valsartan were determined with a LC-MS/MS method. Analysis of variance (ANOVA) was performed on the ln-transformed data for AUC_{0-t} and C_{max}. The study was conducted between 25/10/2024 and 27/11/2024.

Results

The results from the pharmacokinetic and statistical analysis are presented below.

Table 1. Pharmacokinetic parameters (non-transformed values; arithmetic mean ± SD, t_{max} median, range) for sacubitril, n=48 (Test n=94, Reference n=93)

Treatment	AUC_{0-t} ng*h/ml	C_{max} ng/ml	t_{max} h
Test	**712.9 ± 170.8**	**771.9 ± 359.6**	**0.50 (0.17-3.00)**
Reference	**696.4 ± 154.4**	**815.2 ± 346.8**	**0.50 (0.33-3.00)**
***Ratio (90% CI)**	**101.42 (98.55-104.38)**	**91.52 (82.00-102.15)**	**-**

AUC_{0-t} area under the plasma concentration-time curve from time zero to t hours
C_{max} maximum plasma concentration
t_{max} time for maximum plasma concentration

**calculated based on ln-transformed data*

Table 2. Pharmacokinetic parameters (non-transformed values; arithmetic mean ± SD, t_{max} median, range) for valsartan, n=48 (Test n=94, Reference n=93).

Treatment	AUC_{0-t} ng*h/ml	C_{max} ng/ml	t_{max} h
Test	**10232.6 ± 3387.6**	**1530.3 ± 497.6**	**1.67 (1.00-4.00)**
Reference	**10338.6 ± 3522.2**	**1625.9 ± 521.0**	**1.33 (1.00-4.50)**
***Ratio (90% CI)**	**96.61 (90.32-103.33)**	**90.45 (83.56-97.90)**	**-**

AUC_{0-t} area under the plasma concentration-time curve from time zero to t hours
C_{max} maximum plasma concentration
t_{max} time for maximum plasma concentration

**calculated based on ln-transformed data*

For sacubitril and valsartan AUC_{0-t} and C_{max} the 90% confidence interval for the ratio of the test and reference products fell within the conventional acceptance range of 80.00-125.00%.

Study 63924 (97 mg/103 mg)

Methods

This was a two-treatment, four-period, two-sequence single-dose crossover, fully replicate bioequivalence study conducted in 48 healthy volunteers, comparing Sacubitril/Valsartan, 97 mg/103 mg, film-coated tablet with Entresto, 97 mg/103 mg, film-coated tablet under fasting conditions. Blood samples for concentration analysis were collected pre-dose and up to 48 hours post-dose. Plasma concentrations of sacubitril and valsartan were determined with a LC-MS/MS method.

Analysis of variance (ANOVA) was performed on the ln-transformed data for AUC_{0-t} and C_{max}. The study was conducted between 28/10/2024 and 06/12/2024.

Results
The results from the pharmacokinetic and statistical analysis are presented below.

Table 3. Pharmacokinetic parameters (non-transformed values; arithmetic mean ± SD, t_{max} median, range) for sacubitril, n=48 (Test n=94, Reference n=91).

Treatment	AUC_{0-t} ng*h/ml	C_{max} ng/ml	t_{max} h
Test	**2542.2 ± 641.0**	**2353.4 ± 976.2**	**0.67 (0.33-3.00)**
Reference	**2517.5 ± 623.8**	**2308.1 ± 1039.1**	**0.67 (0.33-3.00)**
***Ratio (90% CI)**	**99.56 (97.32-101.85)**	**100.26 (91.45-109.92)**	**-**

AUC_{0-t} area under the plasma concentration-time curve from time zero to t hours
C_{max} maximum plasma concentration
t_{max} time for maximum plasma concentration

**calculated based on ln-transformed data*

Table 4. Pharmacokinetic parameters (non-transformed values; arithmetic mean ± SD, t_{max} median, range) for valsartan, n=48 (Test n=94, Reference n=91).

Treatment	AUC_{0-t} ng*h/ml	C_{max} ng/ml	t_{max} h
Test	**28627.5 ± 11819.5**	**4417.1 ± 1631.8**	**1.67 (1.00-4.50)**
Reference	**29108.5 ± 12511.2**	**4499.0 ± 1735.3**	**1.67 (1.00-4.50)**
***Ratio (90% CI)**	**97.71 (90.97-104.94)**	**98.58 (91.27-106.48)**	**-**

AUC_{0-t} area under the plasma concentration-time curve from time zero to t hours
C_{max} maximum plasma concentration
t_{max} time for maximum plasma concentration

**calculated based on ln-transformed data*

For sacubitril and valsartan AUC_{0-t} and C_{max} the 90% confidence interval for the ratio of the test and reference products fell within the conventional acceptance range of 80.00-125.00%.

A biowaiver was sought for the additional strength of 49 mg/51 mg.

Discussion and overall conclusion
The bioequivalence studies and the statistical evaluation were in accordance with accepted standards for bioequivalence testing, as stated in the Guideline on the investigation of bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1) and ICH M13A Guideline on bioequivalence for immediate-release solid oral dosage forms (EMA/CHMP/ICH/953493/2022). The bioanalytical methods were adequately validated.

Based on the submitted bioequivalence studies, Sacubitril/Valsartan Reddy is considered bioequivalent with Entresto.

Absence of studies with the additional strength of 49 mg/51 mg is acceptable, as all conditions for biowaiver for additional strength(s), as described in the Guideline on the investigation of

bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1) are fulfilled and since the pharmacokinetics of sacubitril and valsartan is linear over the dose range of 24 mg sacubitril/26 mg valsartan to 97 mg sacubitril/103 mg valsartan.

Pharmacovigilance system
Proposed MAH:
Reddy Holding GmbH (SE)
betapharm Arzneimittel GmbH (DE)
Dr. Reddys Laboratories Romania S.R.L. (RO)

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

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 Reddy.

Part II Safety specification
The submitted Risk Management Plan, version 0.2 signed 2025-08-20 included the following summary of safety concerns:

Table SVIII.1: Summary of safety concerns

List of important risks and missing information	
Important identified risks	Embryo-fetal toxicity/lethality
Important potential risks	Neonatal/infantile toxicity through exposure from breast milk
	Cognitive impairment
Missing information	Long term use of sacubitril/valsartan in HF patients

Part III Pharmacovigilance Plan

Routine pharmacovigilance is suggested and no additional pharmacovigilance activities are proposed by the applicant, which is endorsed.

Part V Risk minimisation measures
Routine risk minimisation is suggested and no additional risk minimisation activities are proposed by the applicant, which is endorsed.

Part VI Summary of the RMP

The Summary of the RMP is endorsed.

Conclusion RMP assessment
The submitted Risk Management Plan, version 0.2 signed 2025-08-20 is considered acceptable.

The MAH shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the Marketing Authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the RMS;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

If the dates for submission of a PSUR and the update of a RMP coincide, they can be submitted at the same time, but via different procedures.

Periodic Safety Update Report (PSUR)
Active substance is currently listed in the published EURD list

With regard to PSUR submission, the MAH should take the following into account:

- PSURs shall be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal. Marketing authorisation holders shall continuously check the European medicines web-portal for the DLP and frequency of submission of the next PSUR.

- For medicinal products authorized under the legal basis of Article 10(1) or Article 10a of Directive 2001/83/EC, no routine PSURs need to be submitted, unless otherwise specified in the EURD list.

- In case the active substance will be removed in the future from the EURD list because the MAs have been withdrawn in all but one MS, the MAH shall contact that MS and propose DLP and frequency for further PSUR submissions together with a justification.

Common renewal date
The common renewal date will be 5 years after closure of the DCP.

IV. BENEFIT RISK ASSESSMENT

The quality of the generic product, Sacubitril/Valsartan Reddy, is found adequate. There are no objections to approval of Sacubitril/Valsartan Reddy, from a non-clinical and clinical point of view. Bioequivalence between the test and reference product has been adequately demonstrated. The product information is acceptable. The benefit/risk is considered positive, and the application is therefore recommended for approval.

V. RECOMMENDATIONS AND CONDITIONS FOR MARKETING AUTHORISATION AND PRODUCT INFORMATION

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

Post approval commitments
N/A

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

N/A

V.3 Summary of Product Characteristics (SmPC)

The approved SmPC is available in the MRI Product Index.

V.4 Package Leaflet (PL)

V.4.1 Package Leaflet

The approved PL is available in the MRI Product Index.

V.4.2 Assessment of User Testing

A user consultation with target patient groups on the package information leaflet (PL) has been performed on the basis of a bridging report making reference:

- Sitagliptin 25 mg, 50mg, 100 mg film-coated tablets for layout
- Entresto 24 mg/26 mg_49 mg/51 mg_97 mg/103 mg film-coated tablets for content

The bridging report submitted by the applicant has been found acceptable.

VI. STEPS TAKEN AFTER THE FINALISATION OF THE INITIAL PROCEDURE - SUMMARY

Procedure number	Scope	Product Information affected (Yes/No)	Date of end of procedure	Approval/ non approval	Summary/ Justification for refuse
-	-	-	-	-	-