COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Public Assessment Report

Scientific discussion

Brivaracetam Xiromed 10 mg, 25 mg, 50 mg, 75 mg and 100 mg film-coated tablets (brivaracetam)

NL/H/6561/001-005/DC

Date: 9 December 2025

This report reflects the scientific discussion for the approval of Brivaracetam Xiromed 10 mg, 25 mg, 50 mg, 75 mg and 100 mg film-coated tablets. The procedure was finalised on 28 May 2025 in Finland (FI/H/1311/001-005/DC). After a transfer on 31 October 2025, the current RMS is the Netherlands. As a result, the product name, procedure number and layout have been updated in this report. For information on other changes after the finalisation date please refer to the 'steps taken after finalisation' at the end of this PAR.

List of abbreviations

ASMF	Active Substance Master File
CEP	Certificate of Suitability to the monographs of the European Pharmacopoeia
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
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
ICH	International Conference of Harmonisation
MAH	Marketing Authorisation Holder
Ph.Eur.	European Pharmacopoeia
PL	Package Leaflet
RH	Relative Humidity
RMP	Risk Management Plan
RMS	Reference Member State
SmPC	Summary of Product Characteristics
TSE	Transmissible Spongiform Encephalopathy

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have granted a marketing authorisation for Brivaracetam Xiromed (brivaracetam) 10 mg, 25 mg, 50 mg, 75 mg and 100 mg film-coated tablets, from Medical Valley Invest AB.

The product is indicated as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in adults, adolescents and children from 2 years of age with epilepsy.

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

The marketing authorisation has been granted pursuant to Article 10(1) of Directive 2001/83/EC. The reference medicinal products are Briviact 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg film-coated tablets from UCB Pharma S.A., authorised by the European Union through centralised procedure in 2016.

II. QUALITY ASPECTS

II.1 Introduction

The finished product is presented as film-coated tablets containing 10 mg, 25 mg, 50 mg, 75 mg, or 100 mg brivaracetam as active substance. The tablets are packed in PVC/PCTFE(Aclar)-Aluminium blisters, PVC/PE/PVDC-Aluminium blisters, or HDPE bottles.

The chemical-pharmaceutical documentation and Quality Overall Summary in relation to Brivaracetam Xiromed 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg film-coated tablets are of sufficient quality in view of the present European regulatory requirements.

II.2 Drug Substance

Brivaracetam has a monograph (no. 3139) in the European Pharmacopoeia. Active Substance Master File of brivaracetam has been provided.

Brivaracetam is white or almost white powder that is very soluble to freely soluble in water and in anhydrous ethanol, and practically insoluble in heptane.

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

Manufacturing process

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

Quality control of drug substance
The active 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 of drug substance
Stability studies confirm the retest period.

II.3 Medicinal Product

Pharmaceutical development
The finished product is formulated using excipients listed in section 6.1 in the Summary of Product Characteristics.

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

Quality control of drug product
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 of drug product
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.

II.4 Discussion on chemical, pharmaceutical and biological aspects

Sufficient data on the manufacture, control and stability of the active substance and the finished products have been provided demonstrating a suitable reproducible quality of the proposed formulations. The documentation submitted is of sufficient quality in view of the present European regulatory requirements. Therefore, marketing authorisation has been recommended from the chemical-pharmaceutical point of view.

III. NON-CLINICAL ASPECTS

III.1 Pharmacology, pharmacokinetics and toxicology

Brivaracetam Xiromed film-coated tablets contain 10 mg, 25 mg, 50 mg, 75 mg or 100 mg brivaracetam as active substance. Brivaracetam displays a high and selective affinity for synaptic vesicle protein 2A (SV2A), a transmembrane glycoprotein found at presynaptic level in neurons and in endocrine cells. Although the exact role of this protein remains to be elucidated it has been shown to modulate exocytosis of neurotransmitters. Binding to SV2A is believed to be the primary mechanism for brivaracetam anticonvulsant activity.

The pharmacodynamic, pharmacokinetic and toxicological properties of brivaracetam are well known. As brivaracetam is a widely used, well-known active substance, the applicant has not provided additional studies and further studies are not required. Overview based on literature review is, thus, appropriate.

III.2 Ecotoxicity/environmental risk assessment (ERA)

The Applicant submitted an environmental risk assessment (ERA) as part of the application. The Log Kow of 1.5 at pH 7 indicates that the potential for bioaccumulation of brivaracetam in biota is considered low, and further screening for persistence, bioaccumulation and toxicity (PBT) is not strictly required.
For Fpen refinement the open statistics of the Social Insurance Institution of Finland (KELA), Finland's national authority, were searched for changes in the annual numbers of new drug reimbursement rights for epilepsy in people ≥20 years old between the years 1986 and 2019 (Sipilä and Kälviäinen, 2022). This is considered a valid source of incidence of epilepsy in Finland. For environmental fate and aquatic toxicity data, Briviact Assessment report EMA/CHMP/822086/2015 and FASS environmental information for Briviact, UCB Nordic, (2024) were used as references. While cross-reference to public assessment reports such as EPARs of the originator is not acceptable without the consent from the originator it is acceptable to use FASS environmental information for Briviact.
PECSW 0.0516 µg/L was above 0.01 µg/L threshold. However, the Risk Characterization Ratio (R) is lower than 1, supporting a lack of risk of brivaracetam to the environment in the geographic region considered in the assessment (Finland).

Summary of main study results

Table 1.

Substance (INN/Invented Name): brivaracetam			
CAS-number (if available): 357336-20-0			
PBT screening		Result	**Conclusion**
Bioaccumulation potential- log K_{ow}	OECD107	1.5 at pH=07	Potential PBT N
PBT-assessment			
Parameter	**Result relevant for conclusion**		**Conclusion**
Bioaccumulation	log K_{ow}	1.5 at pH=07	not B
	BCF		B/not B
Persistence	DT50 or ready biodegradability	$DT_{50,\ water}$ = 14.1.-15.1 days $DT_{50,\ sediment}$= 14.3.-21.2 days $DT_{50,\ whole\ system}$= 16.5-18.8. days % shifting to sediment >10% after 14 days	P
Toxicity	NOEC or CMR		not T
PBT-statement :	The compound is not considered as PBT nor vPvB		
Phase I			
Calculation	**Value**	**Unit**	**Conclusion**

PEC surface water, refined (prevalence)	0.0516	µg/L	> 0.01 threshold Y
Other concerns (e.g. chemical class)			N
Phase II Physical-chemical properties and fate			
Study type	**Test protocol**	**Results**	**Remarks**
Adsorption-Desorption	OECD 121	K_{oc} =20.9 mLg	Max value: 10000
Ready Biodegradability Test	OECD 301B	<60% degradation over 10 days	Not readily biodegradable
Aerobic and Anaerobic Transformation in Aquatic Sediment systems	OECD 308	$DT_{50, water}$ =14.1.-15.1 days $DT_{50, sediment}$ =14.3.-21.2 days $DT_{50, whole\ system}$ =16.5-18.8. days % shifting to sediment =	

Phase IIa Effect studies					
Study type	**Test protocol**	**Endpoint**	**value**	**Unit**	**Remarks**
Algae, Growth Inhibition Test/*Species*	OECD 201	NOEC 3 days	100,000	µg/L	*Pseudokirchneriella subcapitata*
Daphnia sp. Reproduction Test	OECD 211	NOEC 21 days	100,000	µg/L	*Daphnia magna*
Fish, Early Life Stage Toxicity Test/*Species*	OECD 210	NOEC 35 days	10,000	µg/L	*Pimephales promelas*
Activated Sludge, Respiration Inhibition Test	OECD 209	NOEC	100 mg/L	µg/L	
Phase IIb Studies					
Sediment dwelling organism	OECD219	NOEC	100	mg/kg	*Chrironomus reparius*

Conclusions on studies:
Brivaracetam is not a PBT substance. Considering the above data, brivaracetam is not expected to pose a risk to the environment.

III.3 Discussion on the non-clinical aspects

As brivaracetam is a well-known active substance, the nonclinical overview based on literature is considered appropriate and no further studies are warranted to support the marketing authorisation. As for all generics, abbreviated data is considered adequate and there is no need to repeat the non-clinical studies already conducted with the originator product.

The non-clinical overview on the non-clinical pharmacology, pharmacokinetics and toxicology has been written by a suitably qualified person and it is considered satisfactory. In addition, an acceptable environmental risk assessment concerning brivaracetam has been performed.

The non-clinical sections of the Summary of Product Characteristics (SmPC) are in line with those of the reference product.

There are no objections to approval of Brivaracetam Xiromed 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg film-coated tablets from a non-clinical point of view.

IV. CLINICAL ASPECTS

IV.1 Introduction

The marketing authorisation application of Brivaracetam Xiromed 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg film-coated tablets has been made on the basis of Article 10(1) of Directive 2001/83/EC, as amended.

Brivaracetam Xiromed 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg film-coated tablets is proposed to be used for the same indications, via same route of administration and with the same dosage as approved for the reference product, Briviact 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg film-coated tablets.

The applied therapeutic indications:
Brivaracetam Xiromed is indicated as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in adults, adolescents and children from 2 years of age with epilepsy.

The applied posology:
The physician should prescribe the most appropriate formulation and strength according to weight and dose.

The recommended posology for adults, adolescents and children from 2 years of age is summarised in the following table. The dose should be administered in two equally divided doses, approximately 12 hours apart.

Recommended starting dose	**Recommended maintenance Dose**	**Therapeutic dose range***
Adolescents and children weighing 50 kg or more, and adults		
50 mg/day (or 100 mg/day)**	100 mg/day	50 - 200 mg/day
Adolescents and children weighing from 20 kg to less than 50 kg		
1 mg/kg/day (up to 2 mg/kg/day)**	2 mg/kg/day	1 – 4 mg/kg/day
Children weighing from 10 kg to less than 20 kg		
1 mg/kg/day (up to 2.5 mg/kg/day)**	2.5 mg/kg/day	1 – 5 mg/kg/day

* Based on individual patient response, the dose may be adjusted within this effective dose range.
** Based on physician's assessment of need for seizure control

Adults
The recommended starting dose is either 50 mg/day or 100 mg/day based on physician's assessment of required seizure reduction versus potential side effects. Based on individual patient response and tolerability, the dose may be adjusted in the effective dose range of 50 mg/day to 200 mg/day.

Adolescents and children weighing 50 kg or more
The recommended starting dose is 50 mg/day. Brivaracetam may also be initiated at 100 mg/day based on physician's assessment of need for seizure control. The recommended maintenance dose is 100 mg/day. Based on individual patient response, the dose may be adjusted in the effective dose range of 50 mg/day to 200 mg/day.

Adolescents and children weighing from 20 kg to less than 50 kg
The recommended starting dose is 1 mg/kg/day. Brivaracetam may also be initiated at doses up to 2 mg/kg/day based on physician's assessment of need for seizure control. The recommended maintenance dose is 2 mg/kg/day. Based on individual patient response, the dose may be adjusted in the effective dose range of 1 mg/kg/day to 4 mg/kg/day.

Children weighing from 10 kg to less than 20 kg
The recommended starting dose is 1 mg/kg/day. Brivaracetam may also be initiated at doses up to 2.5 mg/kg/day based on physician's assessment of need for seizure control. The recommended maintenance dose is 2.5 mg/kg/day. Based on individual patient response, the dose may be adjusted in the effective dose range of 1 mg/kg/day to 5 mg/kg/day.

Missed doses
If patients missed one dose or more, it is recommended that they take a single dose as soon as they remember and take the following dose at the usual morning or evening time. This may avoid the brivaracetam plasma concentration falling below the efficacy level and prevent breakthrough seizures from occurring.

Discontinuation
For patients from 16 years of age, if brivaracetam has to be discontinued, it is recommended that the dose is reduced gradually by 50 mg/day on a weekly basis.
For patients below the age of 16 years, if brivaracetam has to be discontinued, it is recommended that the dose is reduced by a maximum of half the dose every week until a dose of 1 mg/kg/day (for patients with a body weight less than 50 kg) or 50 mg/day (for patients with body weight of 50 kg or more) is reached.

After 1 week of treatment at 50 mg/day, a final week of treatment at the dose of 20 mg/day is recommended.

<u>Special populations</u>

Elderly (65 years of age and above)
No dose adjustment is needed in elderly patients (see section 5.2).
The clinical experience in patients ≥ 65 years is limited.

Renal impairment
No dose adjustment is needed in patients with impaired renal function (see section 5.2). Brivaracetam is not recommended in end-stage renal disease patients undergoing dialysis due to lack of data. Based on data in adults, no dose adjustment is necessary in paediatric patients with impaired renal function. No clinical data are available in paediatric patients with renal impairment.

Hepatic impairment
Exposure to brivaracetam was increased in adult patients with chronic liver disease.
In patients with hepatic impairment, the following adjusted doses, administered in 2 divided doses, approximately 12 hours apart, are recommended for all stages of hepatic impairment (see sections 4.4 and 5.2). No clinical data are available in paediatric patients with hepatic impairment.

Age and body weight	**Recommended starting Dose**	**Recommended maximum daily dose**
Adolescents and children weighing 50 kg or more, and adults	50 mg/day	150 mg/day
Adolescents and children weighing from 20 kg to less than 50 kg	1 mg/kg/day	3 mg/kg/day
Children weighing from 10 kg to less than 20 kg	1 mg/kg/day	4 mg/kg/day

Paediatric patients less than 2 years of age
The efficacy of brivaracetam in paediatric patients aged less than 2 years has not yet been established. Currently available data are described in section 4.8, 5.1, and 5.2 but no recommendation on a posology can be made.

Method of administration
Brivaracetam film-coated tablets must be taken orally and swallowed in whole with liquid and may be taken with or without food. Patients not being able to swallow tablets in whole or patients for whom the dose cannot be met with the use of whole tablets should use other pharmaceutical forms containing brivaracetam available on the market.

To support the marketing authorisation application, the applicant has submitted one bioequivalence study with 100 mg strength and a clinical overview based on literature review.

IV.2 Pharmacokinetics

To support the marketing authorisation application, the applicant has submitted one single-dose bioequivalence study under fasting conditions with 100 mg strength (fasting study 22-VIN-0322).

Biowaiver

The biowaiver has been submitted for the 10 mg, 25 mg, 50 mg and 75 mg strengths. A waiver for additional strengths is claimed in accordance with the European Medicines Agency (EMA) Guideline on the Investigation of Bioequivalence CPMP/EWP/QWP/1401/98 Rev. 1 Corr**, since the general biowaiver requirements are met. All strengths are manufactured by the same manufacturing process. The qualitative composition of all strengths are the same and the composition of the strengths are quantitatively proportional. According to the SmPC of the reference product "pharmacokinetics of brivaracetam is dose proportional from 10 mg to at least 600 mg." In vitro dissolution profiles between Brivaracetam 10 mg, 25 mg, 50 mg, 75 mg vs 100 mg strengths are comparable.

Bioequivalence study 22-VIN-0322

The study was an open-label, balanced, randomized, two-treatment, two-period, two-sequence, single-dose, two-way crossover bioequivalence study conducted under fasting conditions with a wash-out period of 5 days between two administrations.

After an overnight fast, a single 100 mg oral dose of either test product (i.e., Brivaracetam 100 mg film-coated tablet) or reference product (i.e., Briviact 100 mg film-coated tablet) was administered as per randomization schedule in each period in the morning.

The blood samples were collected pre-dose (within one hour before dosing) and at 0.167, 0.33, 0.50, 0.667, 0.83, 1.00, 1.25, 1.50, 1.75, 2.00, 2.33, 2.67, 3.00, 4.00, 5.00, 7.00, 9.00, 12.00, 18.00, 24.00, and 36.00 hours post-dose. The plasma concentrations of brivaracetam were analysed with a validated LC-MS/MS method.

The primary PK parameters were AUC0-t and Cmax. Other PK parameters were AUC0-∞, Tmax, t1/2, λz, and AUC_%Extrap_obs

A total of 28 subjects were enrolled and 24 subjects completed the study and were included in the statistical analysis of the brivaracetam.

Criteria for bioequivalence:

Based on the statistical results of 90 % CIs for the geometric least square (LS) means ratio for the PK parameters Cmax and AUC0-t for brivaracetam the conclusions were drawn whether test formulation was bioequivalent to reference formulation. Acceptance range for bioequivalence was 80.00%-125.00% CIs of the geometric LS means ratio of Cmax and AUC0-t for brivaracetam. Results The main PK results are presented in Table below.

Table 2. Pharmacokinetic parameters (non-transformed values; arithmetic mean ± SD, t_{max} median, range)

Treatment	AUC_{0-t} ng/ml/h	$AUC_{0-\infty}$ ng/ml/h	C_{max} ng/ml	t_{max} h
Test	32387.241 ± 5089.2599	34767.941 ± 5906.0619	3165.279 ± 732.9578	0.584 (0.33-3.00)
Reference	32800.107 ± 5222.7333	35292.844 ± 6069.5469	3318.787 ± 702.4774	0.500 (0.33-2.00)
***Ratio (90% CI)**	98.69 97.57-99.83		94.87 88.70-101.48	

AUC_{0-t} Area under the plasma concentration curve from administration to last observed concentration at time t.
$AUC_{0-\infty}$ Area under the plasma concentration curve extrapolated to infinite time.
C_{max} Maximum plasma concentration
t_{max} Time until Cmax is reached

**ln-transformed values*

The 90% CI for geometric LS mean ratio (T/R) were within the acceptance range of 80.00% to 125.00% for the ln-transformed primary PK parameter Cmax and AUC0-t required for concluding bioequivalence between the test and reference formulations.

Safety:
The test and reference products were well tolerated by the subjects under fasting conditions. There were six (06) AEs reported by four (04) subjects. Three (03/06, 50.00%) AEs were reported by two subjects after administration of the test product (T). Three (03/06, 50.00 %) AEs were reported by three subjects after administration of the reference product (R).

All of the AES were mild in nature, possibly related to study drugs and followed-up until resolution. There were no death or any other associated SAE occurred during the conduct of the study.

<u>Conclusion on bioequivalence studies:</u>
Based on the submitted bioequivalence study, Brivaracetam 100 mg film-coated tablets are considered bioequivalent with Briviact 100 mg film-coated tablets.

The results of study 22-VIN-0322 with 100 mg formulation can be extrapolated to other strengths 10 mg, 25 mg, 50 mg, and 75 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 clinical pharmacodynamic studies have been conducted or required.

IV.4 Clinical safety and efficacy

No new safety or efficacy studies have been performed and no further studies are needed. The Applicant submitted a clinical overview based on literature review to summarise the main PK and PD properties as well as the efficacy and safety aspects of brivaracetam. The clinical

overview has been written by a suitably qualified person and it contained adequate review of published clinical data.

IV.5 Risk Management Plan

The Applicant 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 Brivaracetam Medical Valley.

Safety specification

The Applicant proposes the following summary of the safety concerns in the RMP:

Summary of safety concerns	
Important identified risks	• Suicidality (class label for anticonvulsant products)
Important potential risks	• None
Missing information	• Data during pregnancy and lactation • Long-term effects on growth, endocrine function or sexual maturation, neurodevelopment, cognitive and psychomotor development in pediatric patients.

Originator product for brivaracetam is Briviact, which is centrally approved in the EU on 14 January 2016. Safety specification proposed is in accordance with originator product. Proposed safety specification is approvable.

Pharmacovigilance Plan

Routine pharmacovigilance is suggested. Participation in the European and International Registry of Antiepileptic Drugs in Pregnancy (EURAP) is included as routine pharmacovigilance activity in the RMP. This is in accordance with recommendation given by the PRAC in the September 2024 PRAC meeting.

Risk minimisation measures

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

Summary of the RMP

The submitted Risk Management Plan 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.

IV.6 Discussion on the clinical aspects

Based on the submitted bioequivalence study, Brivaracetam Xiromed 100 mg film-coated tablets are considered bioequivalent with Briviact 100 mg film-coated tablets. The results of study 22-VIN-0322 with 100 mg formulation can be extrapolated to other strengths 10 mg, 25 mg, 50 mg, and 75 mg, according to conditions in Guideline on the Investigation of Bioequivalence CPMP/EWP/QWP/1401/98 Rev. 1/Corr*, section 4.1.6.

The clinical overview covering PK, PD, efficacy and safety aspects has been written by a suitably qualified person and it is considered satisfactory.

The clinical sections of the Summary of Product Characteristics (SmPC) are in line with those of the reference product.

There are no objections to approval of Brivaracetam Xiromed 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg film-coated tablets from a clinical point of view.

V. USER CONSULTATION

A user consultation study was performed to confirm the readability of Brivaracetam Xiromed package leaflet (PL). The Member States are of the opinion that the PL of Brivaracetam Xiromed complies with the readability requirements as stated in Articles 59(3), 61(1) and 63(2) of Directive 2001/83/EC as amended.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The marketing authorisation application of Brivaracetam Xiromed 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg film-coated tablets is made on the basis of article 10(1) of Directive 2001/83/EC as amended, and thus, it is based on demonstration of essential similarity with the reference product. To support the abridged application, the Applicant has provided extensive chemical-pharmaceutical documentation, one clinical bioequivalence study and non-clinical and clinical overviews based on literature review.

The chemical-pharmaceutical documentation in relation to the proposed product is of sufficient high quality in view of the present European regulatory requirements. From the chemical-pharmaceutical point of view, the application for Brivaracetam Xiromed 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg film-coated tablets was, thus, approvable.

From the nonclinical and clinical point of view, the application was also considered acceptable. The submitted non-clinical and clinical overviews as well as the environmental risk assessment (ERA) were sufficient. The non-clinical and clinical sections of the SmPC and PL are in line with those approved for the reference product and thus, acceptable. Based on the submitted bioequivalence study, Brivaracetam 100 mg film-coated tablets are considered bioequivalent with Briviact 100 mg film-coated tablets. The results of bioequivalence study with 100 mg formulation can be extrapolated to other strengths 10 mg, 25 mg, 50 mg, and 75 mg, according to conditions in Guideline on the Investigation of Bioequivalence CPMP/EWP/QWP/1401/98 Rev. 1/Corr*, section 4.1.6.

As a conclusion, the Member States were of the opinion that benefit-risk ratio of Brivaracetam Xiromed 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg film-coated tablets is positive and approval of marketing authorisation was recommended.

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
-	-	-	-	-	-