Medicines Evaluation Board

Public Assessment Report
Scientific discussion

Posaconazol ELC 100 mg gastro-resistant tablets (posaconazole)

NL/H/5497/001/DC

Date: 7 September 2026

This module reflects the scientific discussion for the approval of Posaconazol ELC 100 mg gastro-resistant tablets. The procedure was finalised on 22 July 2026. 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 Posaconazol ELC 100 mg gastro-resistant tablets, from ELC Group s.r.o.

The product is indicated for use in the treatment of the following invasive fungal infections in adults and paediatric patients from 2 years of age weighing more than 40 kg:

- Invasive aspergillosis;
- Fusariosis in patients with disease that is refractory to amphotericin B or in patients who are intolerant of amphotericin B;
- Chromoblastomycosis and mycetoma in patients with disease that is refractory to itraconazole or in patients who are intolerant of itraconazole;
- Coccidioidomycosis in patients with disease that is refractory to amphotericin B, itraconazole or fluconazole or in patients who are intolerant of these medicinal products.

Refractoriness is defined as progression of infection or failure to improve after a minimum of 7 days of prior therapeutic doses of effective antifungal therapy.

The product is also indicated for prophylaxis of invasive fungal infections in adults and paediatric patients from 2 years of age weighing more than 40 kg:

- Patients receiving remission-induction chemotherapy for acute myelogenous leukaemia (AML) or myelodysplastic syndromes (MDS) expected to result in prolonged neutropenia and who are at high-risk of developing invasive fungal infections;
- Hematopoietic stem cell transplant (HSCT) recipients who are undergoing high-dose immunosuppressive therapy for graft versus host disease and who are at high-risk of developing invasive fungal infections.

Please refer to the Summary of Product Characteristics of posaconazole oral suspension for use in oropharyngeal candidiasis.

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 bioequivalence studies under fasting and fed conditions. See Section V. Clinical aspects.

In this decentralised procedure the reference medicinal product is Noxafil 100 mg gastro-resistant tablets. Noxafil has been authorised as an oral suspension in the EEA via the centralised procedure EU/1/05/320 by Merck Sharp & Dohme B.V. since 25 October 2005. The 100 mg gastro-resistant tablet has been registered in The Netherlands as additional pharmaceutical form via a line-extension since 23 April 2014.

This application has been assessed with The Netherlands as Reference Member State (RMS) and France, Germany, Italy and Spain as concerned Member States (CMS).

Assessment of similarity with authorised orphan medicinal product(s) under market exclusivity
According to Article 8(1) of Regulation (EC) No 141/2000, no marketing authorisation can be granted for a product similar to an orphan medicinal product for a period of ten years, when this concerns a similar medicinal product with the same therapeutic indication. Therefore, the MAH has provided a similarity assessment between Posaconazol ELC and the current orphan product authorised in the EU. This orphan product and its (relevant) indications are:

- Cresemba (isavuconazole), MAH: Basilea Pharmaceutica Deutschland GmbH, EU product number: EU/1/15/1036, EU orphan designation number: EU/3/14/1284, designated orphan indication: Treatment of invasive aspergillosis. Date of EU decision: 19 October 2015.

The assessment included the comparison of the therapeutic indication, active substance, mechanism of action and principal (molecular) structure. After consideration of the MAH arguments, Posaconazol ELC is considered not similar to the orphan product based on the principal molecular structure.

Therefore, the existence of any market exclusivity for Cresemba, in the treatment of invasive aspergillosis, does not prevent the granting of the marketing authorisation for Posaconazol ELC.

II.2. About the product

Pharmaco-therapeutic group (ATC Code): J02AC04
Dispensing status: medical prescription

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

Posaconazol ELC is a gastro-resistant tablet. Each gastro-resistant tablet contains 100 mg posaconazole as active substance. The tablets are yellow, coated and oblong, debossed with "100" on one side and plain on the other side.

The excipients are:
Tablet core - hypromellose acetate succinate, microcrystalline cellulose (E460), hydroxypropyl cellulose (E463), croscarmellose sodium (E468), colloidal silicon dioxide (E551) and magnesium stearate (E470b).
Tablet coat - poly(vinyl alcohol) part hydrolysed (E1203), titanium dioxide (E171). macrogol 3350 (E1521), talc (E553B) and iron oxide yellow (E172).

The gastro-resistant tablets are packed in a blister pack of rigid polychlorotrifluoroethylene/ polyvinyl chloride (PCTFE/PVC) film and aluminium blister foil.

III.2. Active substance

The structure of the active substance has been adequately proven and its physico-chemical properties are sufficiently described. The active substance is posaconazole, an established active substance not described in the European Pharmacopoeia (Ph.Eur.). Posaconazole exhibits polymorphism, form 1 is consistently used. Posaconazole form 1 is a white tot off-white powder, freely soluble in dichloromethane, DMSO and NMP, slightly soluble in acetonitrile, sparingly soluble in methanol and acetone, and very slightly soluble in ethanol and isopropanol. This compound has four chiral carbons in its chemical structure; hence, it can exhibit optical isomerism. The substance is produced as a single isomer.

Manufacturing process
Posaconazole is obtained with a convergent process which includes five synthetic steps and two purification steps. Three starting materials are proposed of well-defined structure and properties. The manufacture of the active posaconazole 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
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 Substance. The drug substance specification has been established in-house by the MAH in line with the specification by the drug substance supplier, with an additional requirement for particle size distribution. 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 six batches.

Stability of the active substance
Stability data have been submitted for three commercial batches of the active substance in accordance with the applicable European guidelines. Based on the data submitted, the re-test period for the active substance was confirmed for 36 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 are explained. Several development studies have been performed related to the quantity of the excipients and the choice of the manufacturing process. Two bioequivalence studies versus the reference product Noxafil have been performed (fed and fasting conditions). Bioequivalence has been demonstrated. Comparative dissolution testing at 3 pHs (pH 1.0, 4.5 and 6.8) has been successfully conducted in support of the bioequivalence study. The effect of 5, 10 and 20% alcohol on *in vitro* dissolution was evaluated, and the effect of alcohol on dose dumping was similar or less than seen for the reference product. Pharmaceutical development has been adequately performed.

Manufacturing process
The manufacturing process consists of dry pre-mixing, hot melt extrusion, milling and sifting, blending, compression, film-coating and packing. The manufacturing process is considered a non-standard process. The manufacturing process has been sufficiently described and critical steps have been identified. The manufacturing process has been validated according to relevant European/ICH guidelines.

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

Control of excipients
The excipients comply with the current version of the Ph.Eur. monograph or with in-house requirements. 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 appearance, dimensions, identification by HPLC and UV, identification of yellow ferric oxide and titanium dioxide, assay, uniformity of dosage units by content uniformity, related substances, dissolution, water content, dissolution, disintegration and microbiological quality. The release and shelf life limits are not identical,

several impurities have different release and shelf life limits. 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. Low 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 four commercial batches from the proposed production site(s) have been provided, demonstrating compliance with the specification.

Stability of the medicinal product

Stability data on the product have been provided for four production batches stored at 25°C/ 60% RH (36 months) and 40°C/75% RH (6 months). The stability was tested in accordance with applicable ICH guidelines. The photostability study was conducted on two drug product samples: one directly exposed to light and one wrapped in aluminium (dark control). The results showed that the product is stable when exposed to light. Based on the data submitted, a shelf life of 3 years was granted. The labelled storage conditions are: “This medicinal product does not require any special storage conditions.”

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

There are no substance 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 Posaconazol ELC has a proven chemical-pharmaceutical quality. Sufficient controls have been laid down for the active posaconazole and medicinal product.

IV. NON-CLINICAL ASPECTS

IV.1. Introduction

Pharmacodynamic, pharmacokinetic and toxicological properties of posaconazole are well known. As posaconazole is a widely used, well-known active posaconazole, 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 start of the assessment procedure, before 1 September 2024, the revised ERA guideline (EMEA/CHMP/SWP/4447/00 Rev. 1- Corr.*) was not yet applicable. Therefore the conclusion for this medicinal product was: since Posaconazol ELC 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 Noxafil 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

Posaconazole is a well-known active substance 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 two bioequivalence studies 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 two bioequivalence studies comparing the pharmacokinetic profiles of the test product Posaconazol ELC 100 mg gastro-resistant tablets, ELC Group s.r.o., Czechia and the reference medicinal product Noxafil 100 mg gastro-resistant tablets, Merck Sharp & Dohme B.V., the Netherlands. One study is under fasting and the other under fed conditions. The formula and manufacturing process of the bioequivalence batch was identical to the formula proposed for marketing.

Bioequivalence studies

Study C1B00843 (fasting)

Design

A single-dose, randomised, open label, two-treatment, two-period, two-sequence, crossover, balanced bioequivalence study was carried out under fasted conditions in 56 healthy male subjects, aged 19-44 years. Each subject received a single dose (100 mg) of one of the posaconazole formulations. The tablet was orally administered with 240 mL water after a fasting period of at least 10 hours. There were two dosing periods, separated by a washout period of 7 days.

The plasma concentration time curve was used to assess the rate and extent of absorption. Blood samples were collected pre-dose and at 1, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 8, 9, 10, 12, 14, 16, 24, 48, 72, 96 and 12 hours after administration of the products.

The SmPC recommends administering the product oral, with or without food. The tablets should be swallowed whole with water and should not be crushed, chewed or broken.

The design of the study was considered acceptable as according to the SmPC posaconazole 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
All included 56 subjects completed the study. As per protocol, one subject was excluded from the pharmacokinetic and statistical analysis, due to a pre-dose concentration of posaconazole greater than 5% of the C_{max}. A total of 55 subjects were eligible for pharmacokinetic analysis.

Table 1. Pharmacokinetic parameters (non-transformed values; arithmetic mean ± SD, t_{max} (median, range)) of posaconazole, 100 mg under fasted conditions.

Treatment N=55	AUC_{0-t} (ng.h/mL)	$AUC_{0-\infty}$ (ng.h/mL)	C_{max} (ng/mL)	t_{max} (h)
Test	7141 ± 2729	7511 ± 3034	189 ± 69	6.00 (4.00 – 24.00)
Reference	7679 ± 3095	8032 ± 3376	212 ± 83	6.50 (3.50 – 12.00)
***Ratio** (90% CI)	94.43% (88.52 – 100.73)	94.97% (89.01 – 101.33)	89.96% (84.32 – 95.99)	--

$AUC_{0-\infty}$	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 = 120 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

Study C1B00864 (fed)
Design
A single-dose, randomised, open label, two-treatment, two-period, two-sequence, crossover, balanced bioequivalence study was carried out under fed conditions in 34 healthy male subjects, aged 18-44 years. Each subject received a single dose (100 mg) of one of the two posaconazole formulations. The tablet was orally administered with 240 mL water after an overnight fasting period of at least 10 hours and 30 minutes after a standardised high-fat and high-calorie breakfast (821 calories). There were two dosing periods, separated by a washout period of 10 days.

The plasma concentration time curve was used to assess the rate and extent of absorption. Blood samples were collected pre-dose and at 1, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 8, 9, 10, 12, 14, 16, 24, 48, 72, 96 and 120 hours after administration of the products.

The SmPC recommends administering the product with or without food.

The design of the study was considered acceptable as according to the SmPC posaconazole may be administered without reference to food intake. The bioequivalence study under fed

conditions is in accordance with the 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
Four subjects, out of 34 subjects included, were withdrawn from the study: one subject was withdrawn due to an adverse event (vomiting), one due to protocol violation and two subjects did not report for Period II. A total of 30 subjects were eligible for pharmacokinetic analysis.

Table 2. Pharmacokinetic parameters (non-transformed values; arithmetic mean ± SD, t_{max} (median, range)) of posaconazole, 100 mg under fed conditions.

Treatment N=30	AUC_{0-t} (ng.h/mL)	$AUC_{0-\infty}$ (ng.h/mL)	C_{max} (ng/mL)	t_{max} (h)
Test	11087 ± 2841	11332 ± 3006	373 ± 106	6.50 (4.50 – 14.00)
Reference	10952 ± 2801	11182 ± 2983	374 ± 96	6.50 (4.50 – 12.00)
***Ratio (90% CI)**	101.45% (97.74 – 105.31)	101.55% (97.80 – 105.45)	100.50% (95.16 – 106.15)	--

$AUC_{0-\infty}$	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 = 120 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

Conclusion on bioequivalence studies:
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 studies Posaconazol ELC is considered bioequivalent with Noxafil under both fasted and fed conditions.

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

Posaconazol ELC. At the time of approval, the accepted version of the RMP was version 0.3 with sign-off date 15 May 2026.

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

Important identified risks	None
Important potential risks	None
Missing information	• Safety in children below 2 years of age

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

V.5. Discussion on the clinical aspects

For this authorisation, reference is made to the clinical studies and experience with the reference medicinal product. The MAH demonstrated through two bioequivalence studies that the pharmacokinetic profile of the test 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.

The test consisted of: a pilot test with four participants, followed by two rounds with 10 participants each. The questions covered the following areas sufficiently: traceability, comprehensibility and applicability.
In addition, following the latest revisions to the PL text in line with the reference medicinal product, the MAH evaluated the impact of these changes on the readability and submitted a bridging report making reference to the full user testing report of Posaconazol ELC 100 mg gastro-resistant tablets (NL/H/5497/001/DC).

The results of the user consultation with target patient groups on the PL submitted by the MAH and the additional bridging report show that the PL 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.

VII. POST-APPROVAL COMMITMENTS (PAC's)

Post-approval commitments: not applicable.

VIII. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

Posaconazol ELC 100 mg gastro-resistant tablets has a proven chemical-pharmaceutical quality and is a generic form of Noxafil 100 mg gastro-resistant tablets. Noxafil 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 essential similarity has been demonstrated for Posaconazol ELC with the reference medicinal product, and have therefore granted a marketing authorisation. The decentralised recognition procedure was finalised with a positive outcome on 22 July 2026.

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.