IPAR

Public Assessment Report for a
Medicinal Product for Human Use

Scientific Discussion

Paracetamol 250 mg Suppositories
Paracetamol
PA1721/008/003

The Public Assessment Report reflects the scientific conclusion reached by the Health Products Regulatory Authority (HPRA) at the end of the evaluation process and provides a summary of the grounds for approval of a marketing authorisation for a specific medicinal product for human use. It is made available by the HPRA for information to the public, after deletion of commercially sensitive information. The legal basis for its creation and availability is contained in Article 21 of Directive 2001/83/EC, as amended. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the medicinal product for marketing in Ireland.

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I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the HPRA has granted a marketing authorisation for PARACETAMOL 250 mg SUPPOSITORIES, indicated for:
PARACETAMOL 250 mg SUPPOSITORIES
For the treatment of mild to moderate pain and fever in children.
Paracetamol 250 mg Suppositories are indicated in children from the age of 6 years.
Paracetamol suppositories may be especially useful in patients unable to take oral forms of paracetamol e.g. Post-operative patients or patients with nausea and/or vomiting.

This application for a marketing authorisation was submitted in accordance with Article 10c of Directive 2001/83/EC and is referred to as an 'informed consent' application. This means that the Marketing Authorisation Holder for Paracetamol 80, 125 and 250 mg Suppositories from Phoenix Labs (PAs 1113/004/003, 004 and 001), authorised medicinal products in Ireland, has permitted the applicant to refer to their dossier to obtain an authorisation for Paracetamol 80, 125 and 250 mg Suppositories also from Phoenix Labs (PAs 1113/023/001-003). Paracetamol Suppositories, (PAs 1113/023/001-003) have the same qualitative and quantitative composition in terms of actives substances and the same pharmaceutical form as Paracetamol Suppositories (PAs 1113/004/003, 004 and 001).

The Summary of Product Characteristics for (SmPC) for this medicinal product is available on the HPRA's website at www.hpra.ie.

Name of the product	Paracetamol 250 mg Suppositories
Name(s) of the active substance(s) (INN)	Paracetamol
Pharmacotherapeutic classification (ATC Code)	N02BE01
Pharmaceutical form and strength(s)	
Marketing Authorisation Number(s) in Ireland (PA)	PA1721/008/003
Marketing Authorisation Holder	Phoenix Healthcare Limited, Suite 12, Bunkilla Plaza, Bracetown Business Park, Clonee, Co Meath, D15 WR13, Ireland

II. QUALITY ASPECTS

II.1. Introduction

This informed consent application is for Paracetamol 80, 125 and 250 mg Suppositories.

II.2 Drug substance

The active substance is paracetamol an established active substance described in the European Pharmacopoeia, and is manufactured in accordance with the principles of Good Manufacturing Practice (GMP).

The active substance specification is considered adequate to control the quality and meets current pharmacopoeial requirements. Batch analytical data demonstrating compliance with this specification has been provided.

II.3 Medicinal product

P.1 Composition

Composition of the medicinal product

The excipients in the medicinal product are listed in section 6.1 of the SmPC.
A visual description of the product is included in section 3 of the SmPC.

P.2 Pharmaceutical Development

The product is an established pharmaceutical form and its development is adequately described in the original dossir and in accordance with the relevant European guidelines.

P.3 Manufacture of the Product

The product is manufactured in accordance with the principles of good manufacturing practice (GMP) at suitably qualified manufacturing sites.

The manufacturing process has been validated according to relevant European/ICH guidelines and the process is considered to be sufficiently validated.

P.4 Control of Other Substances (Excipients)

All ingredients comply with Ph. Eur. or are adequately controlled by the manufacturer's specifications.

P.5 Control of Finished Product

The Finished Product Specification is based on the pharmacopoeial monograph for the dosage form, and the tests and control limits are considered appropriate for this type of product.

The analytical methods used are described in sufficient detail and are supported by validation data.

Batch analytical data for a number of batches from the proposed production site have been provided in th original dossier and demonstrate the ability of the manufacturer to produce batches of finished product of consistent quality.

P.6 Packaging material

The approved packaging for this product is described in section 6.5 of the SmPC.

Evidence has been provided that the packaging complies with Ph. Eur./EU legislation for use with foodstuffs requirements.

P.7 Stability of the Finished Product

Stability data on the finished product in the proposed packaging have been provided in accordance with EU guidelines and support the shelf-life and storage conditions listed in sections 6.3 and 6.4 of the SmPC.

II.4 Discussion on Chemical, Pharmaceutical and Biological Aspects

The important quality characteristics of the product are well-defined and controlled. Satisfactory chemical and pharmaceutical documentation has been provided in the original dossier, assuring consistent quality of the product.

III. NON-CLINICAL ASPECTS

III.1 Introduction

This active substance is the same as that present in Paracetamol suppositories on the European market. No new preclinical data have been submitted. As such, no pre-clinical assessment has been made on the application. This is acceptable for this type of application.

III.2 Pharmacology

N/A

III.3 Pharmacokinetics

N/A

III.4 Toxicology

N/A

III.5 Ecotoxicity/environmental risk assessment

This medicinal product is intended for generic substitution and thus an increase in environmental exposure is not anticipated.

III.6 Discussion on the non-clinical aspects

No new nonclinical data was submitted for this application. Abridged applications for generic medicinal products avoid the need for repetitive tests on animals and humans as the active substance has a well-established use.

IV. CLINICAL ASPECTS

IV.1 Introduction

Paracetamol is a well-known active substance with established efficacy and tolerability.

The content of the SmPC approved during the national procedure is in accordance with that accepted for the reference product PARACETAMOL 80, 125 and 250mg SUPPOSITORIES (PAs 1113/004/003, 004 and 001) marketed by Phoenix Labs Unlimited Company.

Paracetamol is a well-known active substance with established efficacy and tolerability. This medicinal product is the same as PARACETAMOL 80, 125 and 250mg SUPPOSITORIES (PAs 1113/004/003, 004 and 001) on the Irish market.

The content of the SmPC approved during the national is in accordance with that accepted for the reference product PARACETAMOL 80, 125 and 250mg SUPPOSITORIES (PAs 1113/004/003, 004 and 001) marketed by Phoenix Labs Unlimited Company.

IV.2 Pharmacokinetics

Absorption
Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. Peak plasma concentrations occur about 2 to 3 hours after rectal administration.

Biotransformation
Paracetamol is primarily metabolised in the liver by conjugation to glucuronide and sulphate.

Elimination
Paracetamol is excreted in the urine mostly as metabolites; 2-4% is excreted unchanged. The average elimination half-life is 1 to 4 hours; half-life is slightly prolonged in neonates (2.2 to 5 hours) and in cirrhotics.

IV.3 Pharmacodynamics

Pharmacotherapeutic Group: Anilides, ATC Code: N02 BE01
Paracetamol is an aniline derivative with analgesic and antipyretic actions.

IV.4 and IV.5 Clinical Efficacy and Safety

Paracetamol is a well-known active substance with established efficacy and tolerability. This medicinal product is the same as PARACETAMOL 80, 125 and 250mg SUPPOSITORIES (PAs 1113/004/003, 004 and 001) on the Irish market.

The content of the SmPC approved during the national procedure is in accordance with that accepted for the reference product marketed in Ireland by Phoenix Labs Unlimited Company.

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 PARACETAMOL 80, 125 and 250mg SUPPOSITORIES.
Routine pharmacovigilance and routine risk minimisation activities are considered sufficient.

Summary of safety concerns

Important identified risks	None
Important potential risks	None
Missing information	None

The Applicant should submit Periodic Safety Update Reports (PSUR) Periodic Safety Update Reports (PSUR) 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.

IV.6 Discussion on the clinical aspects

Paracetamol is a well-known substance and has been widely marketed. As this is an informed consent application no new efficacy or safety data have been submitted. Efficacy and safety is expected to be similar to the reference product PARACETAMOL 80, 125 and 250mg SUPPOSITORIES (PAs 1113/004/003, 004 and 001).

The product information (SmPC and patient leaflet) are identical to those of the reference product.

V. OVERALL CONCLUSIONS

PARACETAMOL 80, 125 and 250mg SUPPOSITORIES (PAs 1113/023/001, 002 and 003) are the same as PARACETAMOL 80, 125 and 250mg SUPPOSITORIES (PAs 1113/004/003, 004 and 001). PARACETAMOL 80, 125 and 250mg SUPPOSITORIES (PAs 1113/004/003, 004 and 001) are well-known medicinal products with a proven chemical-pharmaceutical quality and an established favourable efficacy and safety profile.

The MAH has provided written confirmation that systems and services are in place to ensure compliance with their pharmacovigilance obligations.

The HPRA, on the basis of the data submitted considered that PARACETAMOL 80, 125 and 250mg SUPPOSITORIES (PAs 1113/023/001, 002 and 003) were the same as the reference product and therefore granted a marketing authorisation.

VI. REVISION DATE

May 2025

VII. UPDATES

SCOPE	PROCEDURE NUMBER	PRODUCT INFORMATION AFFECTED	DATE OF START OF PROCEDURE	DATE OF END OF PROCEDURE
New National	CRN00CVN7	SmPC, IPAR and PIL	14/02/2025	13/02/2030
Transfer	CRN00G98F	SmPC section 7, 8, 10 Package Leaflet New MA Holder: Phoenix Healthcare Limited	N/A	16/05/2025

		New PA number: PA1721/008/003		