IPAR

Public Assessment Report for a
Medicinal Product for Human Use

Scientific Discussion

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 IMB has granted a marketing authorisation for Tipol suppositories 75mg, 125mg, 250mg, 500mg 1000mg, from Carysfort Healthcare Ltd. on 06th September 2013, for symptomatic treatment of mild to moderate pain and/or fever.
This application for a marketing authorisation was submitted in accordance with Article 10a of Directive 2001/83/EC and is referred to as a 'well established use' application.

The Summary of Product Characteristics for (SPC) for these medicinal products is available on the IMB's website at www.imb.ie

Name of the product	Tipol 75 mg, 125 mg, 250 mg, 500 mg, 1000 mg suppositories
Name(s) of the active substance(s) (INN)	Paracetamol
Pharmacotherapeutic classification (ATC code)	N02BE01 Paracetamol
Pharmaceutical form and strength(s)	75mg, 125mg, 250mg, 500mg & 1000mg, Suppositories
Marketing Authorisation Number(s) in Ireland (PA)	PA1684/002/001-005
Marketing Authorisation Holder	Carysfort Healthcare Ltd.

II. QUALITY ASPECTS

II.1. Introduction

This application is for Tipol 75 mg, 125 mg, 250 mg, 500 mg and 1000 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

The product is a suppository.
Each 75mg suppository contains 75mg paracetamol. Also contains hard fat.
Each 125mg suppository contains 125mg paracetamol. Also contains hard fat.
Each 250mg suppository contains 250mg paracetamol. Also contains hard fat.
Each 500mg suppository contains 500mg paracetamol. Also contains hard fat and soya lecithin.
Each 1000mg suppository contains 1000mg paracetamol. Also contains hard fat and soya lecithin.

P.2 Pharmaceutical Development

The product is an established pharmaceutical form and its development is adequately described 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 paracetamol suppositories 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 and demonstrate the ability of the manufacturer to produce batches of finished product of consistent quality.

P.6 Packaging material

The product is presented as aluminium blister strips.

Evidence has been provided that the blisters comply with Ph. Eur. and 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 demonstrating the stability of the product for 5 years when stored at below 25°C.

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, assuring consistent quality of Tipol 75 mg, 125 mg, 250 mg, 500 mg and 1000 mg suppositories.

III. NON-CLINICAL ASPECTS

III.1 Introduction

This active substance has been available on the European/Irish market for more than 25 years. Preclinical data have been superseded by clinical experience and therefore no preclinical assessment report is available. This is acceptable for this type of application.

IV. CLINICAL ASPECTS

IV.1 Introduction

Paracetamol is a well known active substance with established efficacy and tolerability.
The content of the summary of product characteristics (SmPC) approved during the national procedure is in accordance with those previously accepted for the active substance, paracetamol.
For this application, the applicant has not provided any clinical studies. This is on the basis that the active substance has been in therapeutic use in the European Union/Community for more than ten years; so called 'well established use'. For the present active substance, paracetamol, the ten year rule is exceeded by many decades. This experience of the active substance is taken to be adequate to establish its safety and efficacy profile and the conduct of further clinical studies is not considered to be necessary.

The Marketing Authorisation Holder submitted a set of documents describing the Pharmacovigilance System, including information on the availability of an EU Qualified Person for Pharmacovigilance (EU-QPPV) and the means for notification of adverse reaction reports in the EU or from a Third Country.

IV.6 Discussion on the clinical aspects

Please see overall conclusion below.

V. OVERALL CONCLUSIONS

Tipol suppositories 75 mg, 125 mg, 250 mg, 500 mg, 1000 mg are generic forms of the well known active substance paracetamol, a medicinal product with a proven chemical-pharmaceutical quality and an established favourable efficacy and safety profile. The SmPC is consistent with those of other authorised medicines containing paracetamol.

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

The IMB, on the basis of the data submitted, considers that Tipol suppositories 75 mg, 125 mg, 250 mg, 500 mg, 1000 mg demonstrate adequate evidence of efficacy for the approved indications as well as a satisfactory risk/benefit profile and therefore granted a marketing authorisation.

VI. REVISION DATE

December 2020

VII. UPDATES

Procedure number	Product Information affected	Date of start of procedure	Date of end of procedure	Approval/non approval
MAH Transfer CRN009JM0	SmPC section 7, 8, 10 Package Leaflet New MA Holder: Clonmel Healthcare Ltd, New PA number:	N/A	04/12/2020	Approved 04/12/2020

	PA0126/331/001			