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

INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the HPRA has granted a marketing authorisation for Buscopan Rx 10mg Coated Tabletsfrom Boehringer Ingelheim Limited on October 2016 for the relief of spasm of the gastrointestinal and genito-urinary tract

This is a duplicate (Article 10 c, informed consent)application for Buscopan Rx 10 mg Coated Tablets (hyoscine butyl bromide) based on the existing Buscopan 10mg prescription only product (PA0007/016/001).

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	Buscopan Rx 10mg Coated Tablets
Name(s) of the active substance(s) (INN)	HYOSCINE BUTYLBROMIDE
Pharmacotherapeutic classification (ATC code)	A03BB01
Pharmaceutical form and strength(s)	10 mg Tablets
Marketing Authorisation Number(s) in Ireland (PA)	PA0007/067/001
Marketing Authorisation Holder	Boehringer Ingelheim Limited

II. QUALITY ASPECTS

II.1. Introduction

This application is for Buscopan Rx 10mg Coated Tablets.

II.2 Drug substance

The application was submitted as an 'informed consent' application. This means that the Marketing Authorisation Holder for Buscopan 10mg Tablets, an authorised medicinal product in Europe, has permitted the applicant to refer to their dossier to obtain an authorisation for Buscopan Rx 10mg Coated Tablets. Therefore, the quality aspects of the drug substance in Buscopan Rx 10mg Coated Tabletsare the same as those for the authorised medicinal product Buscopan 10mg Tablets.

II.3 Medicinal product

The application was submitted as an 'informed consent' application. This means that the Marketing Authorisation Holder for Buscopan 10mg Tablets, an authorised medicinal product in Europe, has permitted the applicant to refer to their dossier to obtain an authorisation for Buscopan Rx 10mg Coated Tablets. Therefore, the quality aspects of the finished product in Buscopan Rx 10mg Coated Tabletsare the same as those for the authorised medicinal product Buscopan 10mg Tablets.

II.4 Discussion on Chemical, Pharmaceutical and Biological Aspects

Buscopan Rx 10mg Coated Tablets has the same qualitative and quantitative composition in terms of active substance and the same pharmaceutical form as the authorised medicinal product Buscopan 10mg Tablets.

III. NON-CLINICAL ASPECTS

III.1 Introduction

This active substance has been available on the Irish market since 1979. This is a duplicate application therefore the pre-clinical data for Buscopan Rx 10mg Coated Tablets is exactly the same as that of Buscopan 10mg Tablets.

III.2 Pharmacology

This is a duplicate application therefore the pharmacology data for Buscopan Rx 10mg Coated Tablets is exactly the same as that of Buscopan 10mg Tablets.

III.3 Pharmacokinetics

This is a duplicate application therefore the pharmacokinetics data for Buscopan Rx 10mg Coated Tablets is exactly the same as that of Buscopan 10mg Tablets.

III.4 Toxicology

This is a duplicate application therefore the toxicology data for Buscopan Rx 10mg Coated Tablets is exactly the same as that of Buscopan 10mg Tablets.

III.5 Ecotoxicity/environmental risk assessment

This is a duplicate application therefore the environmental toxicology data for Buscopan Rx 10mg Coated Tablets is exactly the same as that of Buscopan 10mg Tablets.

III.6 Discussion on the non-clinical aspects

IV. CLINICAL ASPECTS

IV.1 Introduction

This is a duplicate application for Buscopan Rx 10mg Coated Tablets(hyoscine butylbromide) based on the existing Buscopan 10mg Tablets prescription only product (PA0007/016/001). This application is being assessed in parallel with a switch application for Buscopan 10mg Coated Tablets to enable non-prescription pharmacy only sale. The duplicate application has been submitted to continue to allow access to the prescription only product. Hyoscine butylbromide is a well-known active substance with established efficacy and tolerability.

The content of the SmPC approved during this national procedure is the same as that accepted for the current Buscopan SmPC (PA0007/016/001i.e, prior to the switch).

Compliance with GCP, suggested text: N/A.

IV.2 Pharmacokinetics

As this is a duplicate application the pharmacokinetics are exactly the same as those of Buscopan 10mg Tablets

Absorbtion and bioavailabilty, distribution, metabolism, elimination, dose proportionality and time dependence, target/special populations, interactions, relationship between concentration and effect.

IV.3 Pharmacodynamics

As this is a duplicate application the pharmacodynamics are exactly the same as those of Buscopan 10mg Tablets.

IV.4 Clinical Efficacy

As this is a duplicate application the efficacy of Buscopan Rx 10mg Coated Tablets is exactly the same as those of Buscopan 10mg Tablets.

IV.5 Clinical Safety

As this is a duplicate application the safety of Buscopan Rx 10mg Coated Tablets is exactly the same as those of Buscopan 10mg Tablets

Summary of the Pharmacovigilance System
The marketing authorisation holder (MAH) submitted a summary of the Pharmacovigilance System, including confirmation of 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.

Risk Management Plan (usual pharmacovigilance requirements +/- additional requirements)

The schedule for Periodic Safety Update Reports (PSUR) submission should be addressed

IV.6 Discussion on the clinical aspects

As this is a duplicate application for Buscopan Rx 10mg Coated Tablets, which is exactly the same formulation as Buscopan 10mg Tablets, the pharmacokinetics, pharmacodynamics, efficacy and safety as exactly the same as those of Buscopan 10mg Tablets (authorised in Ireland since 1979).

V. OVERALL CONCLUSIONS

As this is a duplicate application for Buscopan Rx 10mg Coated Tablets, which is exactly the same formulation as Buscopan 10mg Tablets, the pharmacokinetics, pharmacodynamics, efficacy and safety as exactly the same as those of Buscopan 10mg Tablets (authorised in Ireland since 1979).
The benefit risk balance is positive.

The SmPC is consistent with that of the unswitched Buscopan 10mg Tablets SmPC.

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

The HPRA consider that the risk/benefit profile for Buscopan Rx 10mg Coated Tablets is satisfactory and have therefore granted a marketing authorisation.

VI. REVISION DATE

October 2021

VII. UPDATES

SCOPE	PROCEDURE NUMBER	PRODUCT INFORMATION AFFECTED	DATE OF START OF PROCEDURE	DATE OF END OF PROCEDURE
MA transfer	CRN00C64T	SmPC section 7, 8, 10 Package Leaflet New MA Holder: Opella Healthcare	N/A	29/10/2021

		France SAS T/A Sanofi New PA number: PA23180/022/001		