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IRISH MEDICINES BOARD

PUBLIC ASSESSMENT REPORT FOR A MEDICINAL PRODUCT FOR HUMAN USE

Scientific discussion

Phorpain Ibuprofen 5% w/w Gel

IBUPROFEN

PA 899/4/4

The Public Assessment Report reflects the scientific conclusion reached by the Irish Medicines Board (IMB) 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 IMB 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 IMB leading to the approval of the medicinal product for marketing in Ireland.

I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the IMB has granted a marketing authorisation for Phorpain Ibuprofen 5% w/w, from Goldshield Pharmaceuticals Ltd on 18th November 2011 for local symptomatic relief of pain and inflammation in the trauma of the tendons, ligaments, muscles and joints and in localised forms of soft tissue rheumatism.

For local symptomatic relief of pain and inflammation in the trauma of the tendons, ligaments, muscles and joints and in localised forms of soft tissue rheumatism

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 Nurofen 5% w/w Gel, an authorised medicinal product in Europe, has permitted the applicant to refer to their dossier to obtain an authorisation for Phorpain Ibuprofen 5% w/w. Phorpain Ibuprofen 5% w/w has the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form as Nurofen 5% w/w Gel. This medicinal product is non prescription (OTC pharmacy) with promotion to the public.

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

Name of the product	Phorpain Ibuprofen 5% w/w Gel
Name(s) of the active substance(s) (INN)	IBUPROFEN
Pharmacotherapeutic classification	ATC Code: M02AA13
Pharmaceutical form and strength(s)	5% w/w Gel
Marketing Authorisation Number(s) in Ireland (PA)	PA 899/4/4
Marketing Authorisation Holder	Mercury Pharmaceuticals Ltd

II QUALITY ASPECTS

II.1. – II.3. Introduction

This application is for Phorpain Ibuprofen 5% w/w Gel.

Since this application is an informed consent of Nurofen 5% w/w Reckitt Benckiser application, the Quality data in support of this product are identical to the up-to-date Quality data of the Nurofen dossier which has been assessed and approved. A more detailed Quality comment is not pertinent.

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 Phorpain Ibuprofen 5% w/w Gel.

III NON-CLINICAL ASPECTS

III.1 Introduction

This active substance is the same as that present in Nurofen 5% w/w Gel Reckitt Benckiser Ireland Ltd, PA 979/32/3 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

Same as that present in Nurofen 5% w/w Gel, PA 979/32/3
Reckitt Benckiser Ireland Ltd, on the European market.

III.3 Pharmacokinetics

Same as that present in Nurofen 5% w/w Gel , PA 979/32/3
Reckitt Benckiser Ireland Ltd, on the European market.

III.4 Toxicology

Same as that present in Nurofen 5% w/w Gel , PA 979/32/3
Reckitt Benckiser Ireland Ltd, on the European market.

III.5 Ecotoxicity/environmental risk assessment

Not applicable

III.6 Discussion on the non-clinical aspects

Not applicable

IV CLINICAL ASPECTS

IV.1 Introduction

Ibuprofen is a well known active substance with established efficacy, tolerability and safety.

The content of the SPC approved is in accordance with that accepted for the reference product Nurofen 5% w/w Gel, PA 979/32/3 marketed by MAH Reckitt Benckiser Ireland Ltd.

As this application is an informed consent no bioequivalence studies are necessary thus bioequivalence testing is waived.

PSURS will be submitted 3 yearly.

IV.2 Pharmacokinetics

The gel product containing ibuprofen diffuses through the skin as a function of time and after 24 hours an application to human skin shows that the dose administered is present in the epidermis and dermis. Percutaneous absorption of this ibuprofen gel is approximately 5% that of oral ibuprofen. Therapeutic concentrations are reached locally; but not systemically.

IV.3 Pharmacodynamics

ATC Code: M02AA13

Ibuprofen is a non-steroidal anti-inflammatory drug which has been tested and proved to be effective as an analgesic, anti-pyretic and anti-inflammatory after systemic administration. When administered as a topical preparation, ibuprofen has been shown to be an effective topical analgesic and anti-inflammatory for the relief of mild to moderate arthritic

pain, muscular pain, backache, sprains, strains, lumbago and fibrositis by virtue of percutaneous absorption.

Experimental data suggest that ibuprofen may inhibit the effect of low dose aspirin on platelets aggregation when they are dosed concomitantly. In one study, when a single dose of ibuprofen 400mg was taken within 8 h before or within 30 min after immediate release aspirin (81mg), a decreased effect of ASA on the formation of thromboxane or platelet aggregation occurred. However, the limitations of these data and the uncertainties regarding extrapolation of ex vivo data to the clinical situation imply that no firm conclusions can be made for regular ibuprofen use, and no clinically relevant effect is considered to be likely for occasional ibuprofen use.

IV.4 Clinical Efficacy

Same as that present in Nurofen 5% w/w Gel, PA 979/32/3
Reckitt Benckiser Ireland Ltd, on the European market.

IV.5 Clinical Safety

Same as that present in Nurofen 5% w/w Gel, PA 979/32/3
Reckitt Benckiser Ireland Ltd, on the European market.

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.

Periodic Safety Update Reports (PSUR) will be submitted every 3 years

IV.6 Discussion on the clinical aspects

As this is an informed consent application no bioequivalence studies are necessary

V OVERALL CONCLUSIONS

Benefit/Risk Assessment and Recommendation

Phorpain Ibuprofen 5% w/w Gel is qualitatively and quantitatively the same as Nurofen 5% w/w Gel. Nurofen 5% w/w Gel is a well-known medicinal product with a proven chemical-pharmaceutical quality and an established favourable efficacy and safety profile.

The IMB, on the basis of the data submitted considered that Phorpain Ibuprofen 5% w/w Gel was the same as the reference product Nurofen 5% w/w Gel and therefore granted a marketing authorisation.