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IRISH MEDICINES BOARD

PUBLIC ASSESSMENT REPORT FOR A MEDICINAL PRODUCT FOR HUMAN USE

Scientific discussion

Corsodyl Freshmint 0.2% w/v Mouthwash

Chlorhexidine digluconate solution 20% w/v

PA 0678/002/005

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 Corsodyl Freshmint 0.2% w/v Mouthwash, from GlaxoSmithKline Consumer Healthcare (Ireland) on 3rd February 2012;

- For the inhibition of the formation of dental plaque.
- As an aid in the treatment and prevention of gingivitis, and in the maintenance of oral hygiene, particularly in situations where tooth brushing cannot be adequately employed (e.g. following oral surgery or in physically or mentally handicapped patients).
- For use in a post-periodontal surgery or treatment regimen to promote gingival healing.
- In the management of aphthous ulceration and oral candidal infections (e.g. denture stomatitis and thrush).

This application for a marketing authorisation was submitted in accordance with Article 8(3) of Directive 2001/83/EC and is referred to as a change of form application to the existing PA 678/2/1 Corsodyl dental gel.

This product is not subject to medical prescription.

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	Corsodyl Freshmint 0.2% w/v Mouthwash
Name(s) of the active substance(s) (INN)	Chlorhexidine digluconate solution, 20% w/v
Pharmacotherapeutic classification (ATC code)	D08AC02
Pharmaceutical form and strength(s)	0.2% w/v
Marketing Authorisation Number(s) in Ireland (PA)	PA 0678/002/005
Marketing Authorisation Holder	GlaxoSmithKline Consumer Healthcare (Ireland) Limited

II QUALITY ASPECTS

II.1. Introduction

This application is for Corsodyl Freshmint 0.2% w/v Mouthwash.

II.2 Drug substance

The active substance is chlorhexidine digluconate, 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 mouthwash which is a clear or slightly opalescent, colourless solution with an odour of peppermint.

Composition of the medicinal product
Chlorhexidine digluconate 0.2% w/v is the active substance. The excipients are glycerol, macrogolglycerol hydroxystearate, sorbitol liquid (non-crystallising), peppermint flavour and purified water

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 guidelines and the process is considered to be sufficiently validated.

P.4 Control of Other Substances (Excipients)

All ingredients comply with Ph. Eur. or comply with the EU regulations and 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 solutions, 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 a multi-dose solution in an amber coloured, polyethylene terephthalate (PET) bottle with a high density polyethylene screwcap.

Evidence has been provided that the bottle complies with Ph. Eur. requirement for plastic containers and closures for pharmaceutical use 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 3 years when not stored above 25°C. The shelf-life after opening is 3 months.

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 Corsodyl Freshmint 0.2% w/v Mouthwash.

III NON-CLINICAL ASPECTS

This active substance has been available on the European and Irish markets for several years. Preclinical data have been superseded by clinical experience and therefore no preclinical assessment report is available.

IV CLINICAL ASPECTS

IV.1 Introduction

Chlorhexidine gluconate is a well known active substance with established efficacy and tolerability. Corsodyl Mouthwash contains 0.2% w/v chlorhexidine gluconate which is an antimicrobial preparation for external use.

It is effective against a wide range of gram negative and gram positive vegetative bacteria, yeasts, dermatophyte fungi and lipophilic viruses. It is active against a wide range of important oral pathogens and is therefore effective in the treatment of many common dental conditions.

IV.2 Clinical Pharmacology

The applicant has outlined the clinical pharmacology of this product using literature references as a basis. As the pharmacokinetics and pharmacodynamics of this substance are well established, this is appropriate.

IV.4 Clinical Efficacy

This application is a line extension to add an alcohol-free solution of chlorhexidine gluconate. The applicant has used bibliographic data to illustrate the efficacy of this solution as compared to the alcohol-containing solution. The supplied bibliographic references are sufficient for this purpose, and as such no additional clinical studies have been provided, nor are needed.

IV.5 Clinical Safety

Chlorhexidine gluconate has a well established safety profile, and the bibliographic data provided do not suggest any change to this profile as applied to the alcohol-free solution.

No additional risk minimisation measures are required for this product outside those necessary for routine pharmacovigilance.

Chlorhexidine gluconate is listed as part of the HMA PSUR worksharing project, and as such the PSUR submission schedule should be harmonised with the data-lock points set out in this procedure.
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

As this active substance has a well established efficacy and safety profile, and as the application is a line extension to an existing product range with no significant changes to the presentation or use of the product, the bibliographic data supplied are sufficient to demonstrate the efficacy and safety of this particular product. As such no additional clinical data have been generated to support this application, and this is acceptable.

V OVERALL CONCLUSIONS

BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

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, considered that Corsodyl Freshmint 0.2% w/v Mouthwash demonstrated 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

February 2012