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HEALTH PRODUCTS REGULATORY AUTHORITY

**PUBLIC ASSESSMENT REPORT FOR A
MEDICINAL PRODUCT FOR HUMAN USE**

Scientific discussion

[Acic Cold Sore 5%w/w Cream](#)

ACICLOVIR

PA0711/017/006

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 HPRa has granted a marketing authorisation for Acic Cold Sore 5% w/w Cream, from Rowex Ltd. on 23rd November 2012 for: the treatment of Herpes simplex virus infections of the skin, lips and face (recurrent herpes labialis).

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 Acic 5% Cream, an authorised medicinal product in Ireland (PA0711/017/001), has permitted the applicant to refer to their dossier to obtain an authorisation for Acic Cold Sore 5% w/w Cream. Acic Cold Sore 5% w/w Cream has the same qualitative and quantitative composition in terms of actives substances and the same pharmaceutical form as Acic 5% Cream.

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	Acic Cold Sore 5% w/w Cream
Name(s) of the active substance(s) (INN)	ACICLOVIR
Pharmacotherapeutic classification (ATC code)	D06BB03
Pharmaceutical form and strength(s)	5% w/w Cream
Marketing Authorisation Number(s) in Ireland (PA)	PA0711/017/006
Marketing Authorisation Holder	Rowex Ltd.

II QUALITY ASPECTS

II.1. Introduction

This application is for Acic Cold Sore 5% w/w Cream.

Since this application is an informed consent of Acic 5% Cream (PA0711/017/001), the Quality data in support of this product is identical to the up-to-date Quality data of the Acic 5% Cream dossier which has been assessed and approved. A more detailed quality comment is not required

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 Acic Cold Sore 5% w/w Cream.

III NON-CLINICAL ASPECTS

III.1 Introduction

Since this application is an informed consent of Acic 5% Cream (PA0711/017/001), the assessment of the non-clinical aspects is not required. The non-clinical data related to this product is identical to that for Acic 5% Cream (PA0711/017/001).

III.2 Pharmacology

N/A

III.3 Pharmacokinetics

N/A

III.4 Toxicology

N/A

III.6 Discussion on the non-clinical aspects

Since this application is an informed consent of Acic 5% Cream (PA0711/017/001), the assessment of the non-clinical aspects is not required. The non-clinical data related to this product is identical to that for Acic 5% Cream (PA0711/017/001).

IV CLINICAL ASPECTS

IV.1 Introduction

Since this application is an informed consent of Acic 5% Cream (PA0711/017/001), the efficacy and safety data in support of this product is identical to the up-to-date efficacy and safety data of the Acic 5% Cream dossier which has been assessed and approved. The pack size for this application is limited to 2g only.

The indication sought for Acic Cold Sore 5% w/w Cream is the treatment of herpes simplex virus infections of the skin, lips and face (recurrent herpes labialis). The applicant is seeking approval for a general sales method of sale and supply.

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

The content of the SPC is acceptable and is similar to that of Acic 5% cream (PA0711/017/001) but without an indication for genital herpes. This is acceptable as the applicant has applied for a general sales designation and genital herpes is not permissible as an indication in the general sales setting. Zovirax Cold Sore Cream is already approved for sale in the general sales setting.

IV.2 Pharmacokinetics

The pharmacokinetics for Cold Sore 5% w/w Cream are the same as that for Acic 5% Cream (PA0711/017/001)

IV.3 Pharmacodynamics

The pharmacodynamics for Cold Sore 5% w/w Cream are the same as that for Acic 5% Cream (PA0711/017/001)

IV.4 Clinical Efficacy

Acic Cream 5% is identical to Acic Cold Sore 5% Cream and has well established efficacy.

IV.5 Clinical Safety

Acic Cream 5% is identical to Acic Cold Sore 5% w/w Cream. The safety and tolerability of Acic Cream 5% is well established.

Risk Management Plan

Acic Cold Sore 5% w/w Cream is a generic product. With the reference product of GlaxoSmithKline Consumer Healthcare (Ireland) Limited marketed under the trade name Zovirax no special important risks or potential risks have been identified which require additional risk minimisation activities (as per Article 8.3 of Directive 2001/83 EC as amended) other than the global pharmacovigilance system. Therefore, no additional activities are proposed for Acic Cold Sore 5% Cream.

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

IV.6 Discussion on the clinical aspects

Since this application is an informed consent of Acic 5% Cream (PA0711/017/001), the efficacy and safety data in support of this product is identical to the up-to-date efficacy and safety data of the Acic 5% Cream dossier which has been assessed and approved. The pack size for this application is limited to 2g only. The SPC and PIL are acceptable.

V OVERALL CONCLUSIONS

Benefit/Risk Assessment and Recommendation

Acic Cold Sore 5% w/w Cream is the same as Acic 5% Cream. Acic 5% Cream (PA0711/017/001), is a well-known medicinal product with a proven chemical-pharmaceutical quality and an established favourable efficacy and safety profile.