IPAR

Public Assessment Report for a Medicinal Product for Human Use

Scientific discussion

Pinaclav 500mg/125 mg Film Coated Tablets

AMOXICILLIN TRIHYDRATE/POTASSIUM CLAVULANATE

PA0281/145/001

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.

I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the HPRA has granted a marketing authorisation for Pinaclav 500mg/125 mg film-coated tablets, from Pinewood Laboratories Ltd on 1st October 2010.

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 Augmentin, an authorised medicinal product in Europe, has permitted the applicant to refer to their dossier to obtain an authorisation for amoxicillin/clavulanic acid. amoxicillin/clavulanic acid has the same qualitative and quantitative composition in terms of actives substances and the same pharmaceutical form as Augmentin.

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

Name of the product	Pinaclav 500 mg/ 125 mg film-coated tablets
Name(s) of the active substance(s) (INN)	AMOXICILLIN TRIHYDRATE POTASSIUM CLAVULANATE
Pharmacotherapeutic classification (ATC code)	J01CR02
Pharmaceutical form and strength(s)	Film-coated tablet 500 mg/125 mg

Marketing Authorisation Number(s) in Ireland (PA)	PA 0281/145/001
Marketing Authorisation Holder	Pinewood Laboratories Ltd T/a Pinewood Healthcare

II QUALITY ASPECTS

II.1. Introduction

This application is for Pinaclav 500 mg/125 mg film-coated tablets.

II.2 Drug substance

The active substances are Amoxicillin Trihydrate and Potassium Clavulanate, established active substances described in the European Pharmacopoeia, and are manufactured in accordance with the principles of Good Manufacturing Practice (GMP)

The active substance specifications are considered adequate to control the quality and meet current pharmacopoeial requirements. Batch analytical data demonstrating compliance with the specifications has been provided.

II.3 Medicinal product

P.1 Composition

White to off-white oval shaped, film-coated tablets debossed with “AC” and a score line on one side and plain on the other side.

Composition of the medicinal product (quantity of active and list of excipients by name only)

Active substances

Amoxicillin Trihydrate Ph. Eur equivalent to Amoxicillin 500.0 mg
Potassium Clavulante Ph. Eur. equivalent to Clavulanic acid 125.0 mg

Excipients
Magnesium Stearate Ph. Eur.
Sodium Starch Glycolate (Type A) Ph. Eur.
Colloidal Anhydrous Silica Ph. Eur.
Microcrystalline Cellulose Ph. Eur.

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. 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 tablets, 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(s) 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 blister pack or a glass bottle.

Evidence has been provided that both packaging types comply with Ph. Eur./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 2 years (blister), 3 years (glass bottle) when stored below 25˚C.

Adventitious Agent Safety

Adventitious viruses

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 Pinaclav 500mg/125 mg film-coated tablets.

III NON-CLINICAL ASPECTS

This active substance is the same as that present in Augmentin 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.

IV CLINICAL ASPECTS

IV.1 Clinical

Amoxicillin/clavulanic acid are well known active substances with established efficacy and tolerability. As this application is under Article 10c of the Directive “informed consent”, no additional clinical studies were submitted to demonstrate the pharmacology efficacy or safety of this product. This is acceptable for this type of application. Reference has been made to the previously assessed dossier of the reference product Augmentin. No reassessment of this dossier has been carried out.

The content of the SPC approved during the national procedure is in accordance with that accepted for the reference product Augmentin marketed by GSK.

Details of the pharmacological aspects of this medicinal product, its clinical efficacy and safety can be found in the authorised version of the SPC.

IV.2 Pharmacovigilance

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

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

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.3 Discussion on the clinical aspects

As this is an application under Article 10c of the Directive “informed consent”, no additional clinical studies have been provided to demonstrate efficacy and safety, and none are required. The product information is in accordance with that of the reference product Augmentin.

V OVERALL CONCLUSIONS

BENEFIT/RISK ASSESSMENT AND RECOMMENDATION
Amoxicillin/Clavulanic Acid 500mg/125mg Film coated Tablets are the same as Augmentin. Augmentin is a well-known medicinal product with a proven chemical-pharmaceutical quality and an established favourable efficacy and safety profile.

The HPRA, on the basis of the data submitted considered that Amoxicillin/Clavulanic Acid 500mg/125mg Film coated Tablets was the same as the reference product and therefore granted a marketing authorisation.

VI REVISION DATE

October 2010