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IRISH MEDICINES BOARD

PUBLIC ASSESSMENT REPORT FOR A MEDICINAL PRODUCT FOR HUMAN USE

Scientific discussion

Azithromycin Pfizer 250 mg Capsules and
Azithromycin Pfizer 200 mg/5 ml Powder for Oral Suspension AZITHROMYCIN
PA 19/93/1-2

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 Azithromycin Pfizer 250 mg Capsules and Azithromycin Pfizer 200 mg/5 ml Powder for Oral Suspension from Pfizer Limited on 19th July 2013 for the treatment of the following infections when known or likely to be due to one or more susceptible microorganisms (see section 5.1 Pharmacodynamic properties):

- bronchitis
- community-acquired pneumonia
- sinusitis
- pharyngitis/tonsillitis (see section 4.4 Special warnings and precautions for use, regarding streptococcal infections)
- otitis media
- skin and soft tissue infections
- uncomplicated genital infections due to Chlamydia trachomatis.

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 Zithromax 250 mg Capsules and Zithromax Powder for Oral Suspension 200 mg/5 ml, authorised medicinal products in Ireland, has permitted the applicant to refer to their dossier to obtain an authorisation for Azithromycin Pfizer 250 mg Capsules and Azithromycin Pfizer 200 mg/5 ml Powder for Oral Suspension. Azithromycin Pfizer 250 mg Capsules and Azithromycin Pfizer 200 mg/5 ml Powder for Oral Suspension have the same qualitative and quantitative composition in terms of actives substance and the same pharmaceutical form as Zithromax 250 mg Capsules and Zithromax Powder for Oral Suspension 200 mg/5 ml.

The Summary of Product Characteristics (SmPC) for each of these medicinal products is available on the IMB's website at www.imb.ie

Name of the product	Azithromycin Pfizer 250 mg Capsules and Azithromycin Pfizer 200 mg/5 ml Powder for Oral Suspension
Name of the active substance (INN)	AZITHROMYCIN as (DIHYDRATE)
Pharmacotherapeutic classification (ATC code)	J01FA
Pharmaceutical forms and strengths	Capsules of 250 mg; powder for oral suspension which contains 200 mg/5 ml when reconstituted.
Marketing Authorisation Numbers in Ireland (PA)	PA 19/93/1-2
Marketing Authorisation Holder	Pfizer Limited

II QUALITY ASPECTS

II.1. Introduction

This application is for Azithromycin Pfizer 250 mg Capsules and Azithromycin Pfizer 200 mg/5 ml Powder for Oral Suspension

II.2 Drug substance

The active substance is azithromycin dihydrate, an established active substance described in the European Pharmacopoeia, which 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

- **Azithromycin Pfizer 250 mg Capsules**

Capsule appearance: White, hard gelatin capsules marked 'Pfizer' and 'ZTM 250' containing a white powder.

Active Substance:
Azithromycin Ph. Eur. 250 mg (as azithromycin dihydrate)

Excipients:
Lactose Anhydrous Ph. Eur.
Maize Starch Ph. Eur.
Magnesium Stearate Ph. Eur.
Sodium Laurilsulfate Ph. Eur.

Capsule shell:
Gelatin Ph. Eur.
Titanium Dioxide Ph. Eur. (E171)

Printing ink:
Black iron oxide (E172)
Shellac

- **Azithromycin Pfizer 200 mg/5 ml Powder for Oral Suspension**

Powder appearance. White powder.
Active substance
Azithromycin Ph. Eur. (as azithromycin dihydrate) 200 mg per 5 ml when reconstituted.

Excipients:
Sucrose
Sodium phosphate tribasic anhydrous
Hydroxypropylcellulose
Xanthan gum
Artificial cherry flavour
Artificial crème de vanilla flavour
Artificial banana flavour

P.2 Pharmaceutical Development

The products are established pharmaceutical forms and their development is adequately described in accordance with the relevant European guidelines.

P.3 Manufacture of the Product

The products are manufactured in accordance with the principles of good manufacturing practice (GMP) at suitably qualified manufacturing sites.

The manufacturing processes have been validated according to ICH guidelines and the processes are considered to be sufficiently validated.

P.4 Control of Other Substances (Excipients/*Ancillary Substances)*

All ingredients comply with the monographs of the European Pharmacopoeia or are adequately controlled by the manufacturer's specifications.

P.5 Control of Finished Product

The finished product specifications are based on the pharmacopoeial monographs for the dosage forms, and the tests and control limits are considered appropriate for these types of products.

The analytical methods used are described in sufficient detail and are supported by validation data.

Batch analytical data have been provided and demonstrate the ability of the manufacturer to produce batches of finished product of consistent quality.

P.6 Packaging material

Azithromycin Pfizer Capsules are available as:
PVC/Aluminium opaque blister strips – 2, 4, or 6 capsules per pack.
PE container with child-resistant closure – 100 capsules per container.

Not all pack-sizes may be marketed.

Azithromycin Pfizer Powder for Oral Suspension is available as 15 ml (600 mg), 22.5 ml (900 mg), 30 ml (1200 mg) polypropylene container with child resistant screw cap (with or without tamper-evident seal), in a carton box. Pack contains a multi-dosing spoon.
15 ml (600 mg) containers also contain a 10 ml oral dosing syringe with detachable adaptor. A sticker for the syringe is appended to the bottle label.

Not all pack sizes may be marketed.

P.7 Stability of the Finished Product

Stability data on the finished products in the proposed packaging configurations have been provided in accordance with EU guidelines and justify the shelf-lives indicated below.

- Azithromycin Pfizer 250 mg Capsules
  Aluminium/PVC blister strips in cartons: 5 years with no special storage conditions.
  PE container with child-resistant closure: 4 years with no special storage conditions.

- Azithromycin Pfizer 200 mg/5 ml Powder for Oral Suspension
  Dry powder: 3 years. Do not store above 30 ºC.
  Once reconstituted with water, the oral suspension has a shelf-life of 5 days. Do not store above 25 °C. Do not refrigerate or freeze.

II.4 Discussion on Chemical, Pharmaceutical and Biological Aspects

The important quality characteristics of the products are well-defined and controlled. Satisfactory chemical and pharmaceutical documentation has been provided, assuring consistent quality of Azithromycin 250 mg Capsules and Azithromycin 200mg/5ml Powder for Oral Suspension.

III NON-CLINICAL ASPECTS

Not applicable.

IV CLINICAL ASPECTS

IV.1 Introduction

Azithromycin is a well known active substance with established efficacy and tolerability. This medicinal product is the same as Zithromax on the European market

The content of the SmPC approved during the national procedure is in accordance with that accepted for the reference product Zithromax marketed by MAH.

IV.2 Pharmacokinetics

N/A

IV.3 Pharmacodynamics

N/A

IV.4 Clinical Efficacy

N/A

IV.5 Clinical Safety

N/A

IV.6 Discussion on the clinical aspects

N/A

V OVERALL CONCLUSIONS

Benefit/Risk Assessment and Recommendation

Azithromycin Pfizer 250 mg Capsules and Azithromycin Pfizer 200 mg/5 ml Powder for Oral Suspension are the same as Zithromax 250 mg Capsules and Zithromax Powder for Oral Suspension 200 mg/5 ml. Zithromax 250 mg Capsules and Zithromax Powder for Oral Suspension 200 mg/5 ml are well-known medicinal products 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 Azithromycin Pfizer 250 mg Capsules and Azithromycin Pfizer 200 mg/5 ml Powder for Oral Suspension were the same as the reference products and therefore granted marketing authorisations.