LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Piperacillin/Tazobactam Reig Jofre
(piperacillin sodium, tazobactam sodium)

SE/H/1867/01-02

This module reflects the scientific discussion for the approval of Piperacillin/Tazobactam Reig Jofre. The Summary Public Assessment Report is based on the day 210 Final Assessment Report written in March 2010 by the previous RMS UK after initial procedure UK/H/1011/01-02/DC. RMS transfer from UK to SE was completed July 2018.

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I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, a marketing authorisation has been granted for Piperacillin/Tazobactam Reig Jofre, 2 g/0,25 g, 4 g/0,5 g, Powder for solution for infusion.

The active substance is piperacillin sodium, tazobactam, piperacillin, tazobactam sodium. A comprehensive description of the indication and posology is given in the SmPC.

For recommendations to the marketing authorisation not falling under Article 21a/22a/22 of Directive 2001/83/EC and conditions to the marketing authorisation pursuant to Article 21a/22a/ 22 of Directive 2001/83/EC to the marketing authorisation, please see section VI.

This is a decentralised application submitted under article 28(3) of directive 2001/83/EC for Piperacillin and Tazobactam 2/0.25g and 4/ 0.5g, Powder for Solution for Injection, with UK as RMS and DK, FI and SE as CMS.

The application is submitted as a generic application under article 10(1) of directive 2001/83/EC, as amended, with Tazocin 2.25g and 4.50g, from Wyeth Lederle authorised in France since Jan 1992, as the reference product. The corresponding brand leader products licensed in the UK are Tazocin ® 2.25g (PL 00011/0292) and Tazocin ® 4.5g (PL 00011/0293), licensed to Wyeth Pharmaceuticals in December 1992.

II. QUALITY ASPECTS

II.1 Drug Substance

The structure of the drug substance has been adequately proven and its physico-chemical properties are sufficiently described.

The manufacture of the drug substance has been adequately described and satisfactory specifications have been provided for starting materials, reagents and solvents.

The drug substance specification includes relevant tests and the limits for impurities and degradation products have been justified. The analytical methods applied are suitably described and validated.

Stability studies confirm the retest period.

II.2 Medicinal Product

The medicinal product is formulated using excipients listed in section 6.1 in the Summary of Product Characteristics.

The manufacturing process has been sufficiently described and critical steps identified.

The tests and limits in the specification are considered appropriate to control the quality of the finished product in relation to its intended purpose.

Stability studies have been performed and data presented support the shelf life and special precautions for storage claimed in the Summary of Product Characteristics, sections 6.3 and 6.4.

III. NON-CLINICAL ASPECTS

No new data have been submitted and none are required for this application.

A formal Environmental Risk Assessment has not been performed as the product is intended for generic substitution. Hence no increase in environmental risk is to be expected compared to that of the reference product.

IV. CLINICAL ASPECTS

Pharmacokinetics
No new data have been submitted and none are required for this application. According to CPMP guidelines, the applicant is not required to submit a bioequivalence study if the product is to be administered as an aqueous intravenous solution containing the same active substance, in the same concentration as the currently authorised product (CPMP/EWP/1401/98, subpoint 5.1.6, Parenteral solutions).

Pharmacodynamics
No novel pharmacodynamic data are supplied or required for this application. The pharmacodynamic claims in the SPC are appropriately consistent with the innovator product. The pharmacodynamic properties of this combination have been extensively studied in the past.

Clinical efficacy
No novel efficacy data are supplied or required for this generic application. However, the applicant has provided a review of clinical trials published in the literature confirming the efficacy of Piperacillin sodium/Tazobactam sodium. The clinical overview establishes the use of Piperacillin sodium/Tazobactam sodium in the treatment of respiratory tract infections (Oizumi et al., 1995), hospital and community acquired pneumonia (Speich et al., 1998), intra-abdominal infections (Wilson and Nord., 1995), neutropenic patients with fever (Hazel et al., 1997; Frauser et al., 1995) and other susceptible bacterial infections (Bryson and Brogden., 1994).

Clinical safety
No novel safety data are supplied or required for this generic application. However, the applicant has provided a review of clinical trials published in the literature confirming the safety of Piperacillin sodium/Tazobactam sodium. No new safety data have been identified.

V. USER CONSULTATION

User testing was accepted in the day 70 Quality Assessment report. The RMS considers that the adoption of text from UK/H/908/01/DC improves the overall safety messages. This is acceptable.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The use of Piperacillin sodium/Tazobactam sodium is well established. It has recognised efficacy and acceptable safety. With regards to the current application, sufficient clinical information has been submitted which includes adequate review of published clinical data. The claim of essential similarity

can be accepted. Overall, the risk: benefit analysis for Piperacillin sodium/Tazobactam sodium is considered favourable and approval is recommended.

List of recommendations not falling under Article 21a/22a/22 of Directive 2001/83/EC in case of a positive benefit risk assessment

N/A

List of conditions pursuant to Article 21a/22a or 22 of Directive 2001/83/EC

N/A

VII. APPROVAL

The decentralised procedure for Piperacillin/Tazobactam Reig Jofre, 2 g/0,25 g, 4 g/0,5 g, Powder for solution for infusion was positively finalised on 2010-03-16.

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Public Assessment Report – Update

Procedure number*	Scope	Product Information affected (Yes/No)	Date of end of procedure	Approval/ non approval	Summary/ Justification for refuse
SE/H/1867/001-002/II/019	Submission of a type II variation C.1.11.b; introduction of an RMP	No	2022-11-15	Approval	

*Only procedure qualifier, chronological number and grouping qualifier (when applicable)

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