IPAR

Public Assessment Report for a
Medicinal Product for Human Use

Scientific Discussion

Meropenem Infomed 1 g powder for solution for injection/infusion
Meropenem Trihydrate
Meropenem Anhydrous
PA23451/001/002

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.

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I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the HPRA has granted a marketing authorisation for Meropenem Infomed 500 mg & 1g powder for solution for injection/infusion, from Infomed Fluids Srl on 7th May 2021 for the treatment of the following infections in adults and children over 3 months of age:
- Pneumonia, including community acquired pneumonia and nosocomial pneumonia.
- Broncho-pulmonary infections in cystic fibrosis
- Complicated urinary tract infections
- Complicated intra-abdominal infections
- Intra- and post-partum infections
- Complicated skin and soft tissue infections
- Acute bacterial meningitis

Meropenem Infomed may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection.

Consideration should be given to official guidance on the appropriate use of antibacterial agents,.

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	Meropenem Infomed 500 mg & 1g powder for solution for injection/infusion
Name(s) of the active substance(s) (INN)	Meropenem Trihydrate
Pharmacotherapeutic classification (ATC code)	J01DH02
Pharmaceutical form and strength(s)	500 mg & 1g powder for solution for injection/infusion
Marketing Authorisation Number(s) in Ireland (PA)	PA23451/001/001-002
Marketing Authorisation Holder	ACS Dobfar S.p.A.
MRP/DCP No.	IE/H/1034/001-002/DC
Reference Member State	IE
Concerned Member State	DE IT MT

II. QUALITY ASPECTS

II.1. Introduction

This application is for Meropenem Infomed 500 mg & 1g powder for solution for injection/infusion.

II.2 Drug substance

The active substance is Meropenem Trihydrate, 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

Composition of the medicinal product Meropenem Infomed 500 mg powder for solution for injection/infusion

Each vial contains meropenem trihydrate equivalent to 500 mg anhydrous meropenem.

The excipients in the medicinal product are listed in section 6.1 of the SmPC.
A visual description of the product is included in section 3 of the SmPC.

Composition of the medicinal product Meropenem Infomed 1g powder for solution for injection/infusion

Each vial contains meropenem trihydrate equivalent to 1 g anhydrous meropenem.

The excipients in the medicinal product are listed in section 6.1 of the SmPC.
A visual description of the product is included in section 3 of the SmPC.

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 and ICH guidelines and the process is considered to be sufficiently validated.

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

All ingredients comply with Ph. Eur.

P.5 Control of Finished Product

The Finished Product Specification is based on the pharmacopoeial monograph for Parenteral preparations/Powders for injections or infusions, 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 approved packaging for this product is described in section 6.5 of the SmPC.

Evidence has been provided that the packaging complies with relevant Ph. Eur. Requirement and EU legislation for use with foodstuffs.

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 and support the shelf-life and storage conditions listed in sections 6.3 and 6.4 of the SmPC.

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 Meropenem Infomed 500 mg & 1g powder for solution for injection/infusion.

III. NON-CLINICAL ASPECTS

III.1 Introduction

This active substance is a generic formulation of Meronem 500 mg, and 1g, Powder for solution for injection or infusion (AstraZeneca), on the European market since 1994. No new preclinical data have been submitted.

The pharmacodynamic, pharmacokinetic and toxicological properties of meropenem are well known. As meropenem is a widely used, well-known active substances, and this is a generic application, the applicant has not provided additional nonclinical studies and further studies are not required. The overview provided based on literature review is thus appropriate.

III.2 Ecotoxicity/environmental risk assessment

The applicant has not provided a full environmental risk assessment (ERA) in accordance with the guideline (CHMP/SWP/4447/00). Instead justification for the absence of a full ERA is supplied.
Since Meropenem Infomed 500 mg & 1g powder for solution for injection/infusion is intended for generic substitution, this will not lead to an increased exposure to the environment. An environmental risk assessment is therefore not deemed necessary.

III.3 Discussion on the non-clinical aspects

The pharmacodynamic, pharmacokinetic and toxicological properties of meropenem are well known. As meropenem is a widely used, well-known active substances, and this is a generic application, the applicant has not provided additional nonclinical studies and further studies are not required. The non-clinical overview on the pre-clinical pharmacology, pharmacokinetics and toxicology provided is adequate. Non-clinical findings are adequately represented in the appropriate sections of the SmPC.

IV. CLINICAL ASPECTS

IV.1 Introduction

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

The content of the SmPC approved during the decentralised procedure is in accordance with that accepted for the reference product Meronem 500 mg, and 1g, Powder for solution for injection or infusion marketed by AstraZeneca.

The product is administered through injection of infusion. No pharmacokinetic study is required to support this application. This is based on the fact that product being parenteral & having the same active in the same concentration as the reference product as outlined in the guideline on bioequivalence-CPMP/EWP/QWP/1401/98 Rev. 1 2010.

IV.2 Pharmacodynamics/ Clinical efficacy/Clinical safety

Pharmacodynamic, pharmacokinetic and efficacy/safety data of the active substance are well known. This is a generic application and no new indications have been applied for.
The applicant has not submitted new clinical information and an overview based on a literature review is therefore appropriate and acceptable to the RMS, in accordance to Directive 83/2001 as amended

Risk Management Plan

The applicant has submitted a risk management plan, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Meropenem 500mg & 1g powder for solution for injection/infusion.
The revised RMP (version 0, revision 3, data lock point 24/01/2021) is acceptable. Routine pharmacovigilance and routine risk minimisation activities are considered sufficient.
The applicant is requested to ensure it maintains the RMP in line with the latest SmPC updates and maintains regular reviews.

Summary of safety concerns

Important identified risks	None
Important potential risks	None
Missing information	None

Periodic Safety Update Report (PSUR)
With regard to PSUR submission, the MAH should take the following into account:

- PSURs shall be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal. Marketing authorisation holders shall continuously check the European medicines web-portal for the DLP and frequency of submission of the next PSUR.
- For medicinal products authorized under the legal basis of Article 10(1) or Article 10a of Directive 2001/83/EC, no routine PSURs need to be submitted, unless otherwise specified in the EURD list.
- In case the active substance will be removed in the future from the EURD list because the MAs have been withdrawn in all but one MS, the MAH shall contact that MS and propose DLP and frequency for further PSUR submissions together with a justification.

IV.6 Discussion on the clinical aspects

Based on the review of the data on quality, safety and efficacy, the RMS considers that the application for Meropenem 0.5g and 1g Powder for solution for injection or infusion for the treatment of the following infections in adults and children over 3 months of age:
- Pneumonia, including community acquired pneumonia and nosocomial pneumonia.
- Broncho-pulmonary infections in cystic fibrosis
- Complicated urinary tract infections
- Complicated intra-abdominal infections
- Intra- and post-partum infections
- Complicated skin and soft tissue infections
- Acute bacterial meningitis

Is approvable.
Meropenem Infomed may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection.
Consideration should be given to official guidance on the appropriate use of antibacterial agents.

V. OVERALL CONCLUSIONS

The benefit risk profile of the product is positive.

VI. REVISION DATE

24.03.2026

VII. UPDATES

This section reflects the significant changes following finalisation of the initial procedure.

SCOPE	PROCEDURE NUMBER	PRODUCT INFORMATION AFFECTED	DATE OF START OF PROCEDURE	DATE OF END OF PROCEDURE
MA transfer	CRN00D8CT	SmPC section 7, 8, 10 Package Leaflet New MA Holder:	N/A	25/11/2022

		ACS Dobfar S.p.A. New PA number: PA23451/001/002		