IPAR

Public Assessment Report for a
Medicinal Product for Human Use

Scientific Discussion

Fusidic acid/Betamethasone Laboratoires Medgen 20 mg/g + 1 mg/g Cream
Fusidic acid
Betamethasone valerate
PA25250/001/001

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.

CONTENTS

I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the HPRA has granted a marketing authorisation for Fusidic acid/Betamethasone Laboratoires Medgen 20 mg/g + 1mg/g Cream, from Laboratoires Medgen on 12th September 2025 for the treatment of inflammatory dermatoses where bacterial infection is present or likely to occur in adults and children over 1 year.

With Ireland as the Reference Member State in this decentralised procedure, Laboratoires Medgen are applying for a marketing authorisation for Fusidic acid/Betamethasone Laboratoires Medgen 20 mg/g + 1 mg/g cream under IE/H/1318/001/DC with BE, ES and LU as CMS.

This decentralised application is submitted under Article 10(3) hybrid application of Directive 2001/83/EC. The active substances, fusidic acid and betamethasone valerate, are not considered new active substances.

A European Reference Medicinal Product is used. The reference product is Fucibet 20 mg/g + 1 mg/g Cream (MAH: LEO Laboratories Ltd) authorised in Ireland since 23 May 1984 (PA0046/040/001).

The medicinal product is subject to prescription which may not be renewed.
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	Fusidic acid/Betamethasone Laboratoires Medgen 20 mg/g + 1 mg/g Cream
Name(s) of the active substance(s) (INN)	Fusidic acid, Betamethasone valerate
Pharmacotherapeutic classification (ATC code)	Corticosteroids, potent, combination with antibiotic; ATC code: D07C C01
Pharmaceutical form and strength(s)	20 mg/g + 1 mg/g Cream
Marketing Authorisation Number(s) in Ireland	PA25250/001/001
Marketing Authorisation Holder	Laboratoires Medgen 24 Rue Erlanger Paris 75016 France
MRP/DCP no.	IE/H/1318/001/DC
Reference Member State	IE
Concerned Member State	BE ES LU

II. QUALITY ASPECTS

II.1. Introduction

This application is for Fusidic acid/Betamethasone Laboratoires Medgen 20 mg/g + 1 mg/g cream.

II.2 Drug substance

There are two active substances, Fusidic acid and Betamethasone Valerate. Both active substances are 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 these specifications have been provided.

II.3 Medicinal product

P.1 Composition

The content of the active substances is stated in section 2 of the SmPC.
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/ICH guidelines and the process is considered to be sufficiently validated.

P.4 Control of Other Substances (Excipients)

All ingredients comply with Ph. Eur.

P.5 Control of Finished Product

The Finished Product Specification is based on the pharmacopoeial monograph for semi-solid preparations for cutaneous application 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 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 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 have been provided, assuring consistent quality of Fusidic acid/Betamethasone Laboratoires Medgen 20 mg/g + 1 mg/g cream.

III. NON-CLINICAL ASPECTS

III.1 Introduction

These active substances are a generic formulation of Fucibet which has been available on the Irish market since 1984. As the pharmacodynamic, pharmacokinetic and toxicological properties of Fusidic Acid and Betamethasone are well known, no new non-clinical data have been submitted. This is acceptable for this type of application.

III.2 Pharmacology

N/A

III.3 Pharmacokinetics

N/A

III.4 Toxicology

N/A

III.5 Ecotoxicity/environmental risk assessment

Betamethasone poses a risk to the aquatic environment. Additional studies on environmental risk assessment for fusidic acid/betamethasone are not deemed necessary. The risk is adequately indicated in sections 5.3 and 6.6 of the SmPC.

III.6 Discussion on the non-clinical aspects

The pharmacodynamic, pharmacokinetic and toxicological properties of fusidic acid and betamethasone are well known. As fusidic acid and betamethasone are well-known active substances, no new non-clinical studies have been provided, and further studies are not required. A non-clinical overview based on literature was provided and is acceptable.

IV. CLINICAL ASPECTS

IV.1 Introduction

Fusidic acid and betamethasone valerate are well-known active substances with established efficacy and tolerability.

The content of the SmPC approved during the decentralised procedure IE/H/1318/001/DC is in accordance with that accepted for the European Reference Product Fucibet 20 mg/g + 1mg/g Cream (MAH: LEO Laboratories Ltd) authorised in Ireland since 23 May 1984 (PA0046/040/001).

To demonstrate therapeutic equivalence to the European Reference Product, the following studies were submitted:

1. Physico-chemical comparison between test and reference products.
2. *In vitro* release study between test and reference products.
3. *In vitro* human skin permeation study to compare skin penetration/permeation between test and reference products.
4. *In vitro/ex vivo* study in infected human skin to compare microbiological activity of fusidic acid between test and reference products.
5. *In vivo* skin blanching study for betamethasone valerate between test and references products.
6. *In vitro* release study between test and reference products at 24 months.

Based on the data package provided, it can be concluded that the proposed product is therapeutically equivalent to the European Reference Product.

IV.2 Pharmacokinetics

There are no data which define the pharmacokinetics of Fusidic acid/Betamethasone Laboratoires Medgen 20 mg/g + 1 mg/g cream following topical administration in man. However, *in vitro* studies show that fusidic acid can penetrate intact human skin. The degree of penetration depends on factors such as the duration of exposure to fusidic acid and the condition of the skin. Fusidic acid is excreted mainly in the bile with little excreted in the urine.

Betamethasone is absorbed following topical administration. The degree of absorption is dependent on various factors including skin condition, site of application and application on large skin areas and under occlusive dressings. Betamethasone is metabolised largely in the liver but also to a limited extent in the kidneys, and the inactive metabolites are excreted with the urine.

IV.3 Pharmacodynamics

Pharmacotherapeutic group: Corticosteroids, potent, combination with antibiotic;
ATC code: D07C C01.

Fusidic acid/Betamethasone Laboratoires Medgen 20 mg/g + 1 mg/g Cream combines the potent topical antibacterial action of fusidic acid with the anti-inflammatory and antipruritic effects of betamethasone valerate.

Fusidic acid and its salts exhibit fat and water solubility properties with strong surface activity and show unusual ability to penetrate intact skin. Concentrations of 0.03 - 0.12 mcg/ml inhibit nearly all strains of Staphylococcus aureus. When applied topically, fusidic acid is active against Streptococci, Corynebacteria, Neisseria and certain Clostridia.

Betamethasone valerate is a potent topical corticosteroid rapidly effective in those inflammatory dermatoses which normally respond to this form of therapy.

IV.4 Clinical Efficacy

The applicant has provided a review of published literature relating to the proposed indication. No new efficacy studies have been submitted, and this is acceptable in keeping with the legal basis of this application.

IV.5 Clinical Safety

The applicant has provided a review of published literature relating to bacterial resistance and local tolerance. No new safety studies have been submitted, and this is acceptable in keeping with the legal basis of this application.

The SmPC captures the known relevant safety information.

Risk Management Plan
A Risk Management Plan, version 1.0, dated 12/10/2023, has been submitted, 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 Fusidic acid/ Betamethasone Laboratoires Medgen 20 mg/g + 1 mg/g cream. It is concluded that routine pharmacovigilance and risk minimization measures are sufficient.

Summary table of safety concerns as approved in the RMP:

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

This decentralised application is submitted under Article 10(3) hybrid application of Directive 2001/83/EC. The active substances, fusidic acid and betamethasone valerate have a well-established efficacy and safety profile.

The European Reference Product is Fucibet 20 mg/g + 1 mg/g Cream (MAH: LEO Laboratories Ltd) authorised in Ireland since 23 May 1984 (PA0046/040/001).

Based on the data package provided, it is concluded that the proposed product is therapeutically equivalent to the European Reference Product.

V. OVERALL CONCLUSIONS

Fusidic acid/Betamethasone Laboratoires Medgen 20 mg/g + 1 mg/g Cream is a generic form of Fucibet 20 mg/g + 1 mg/g Cream (MAH: LEO Laboratories Ltd) authorised in Ireland since 23 May 1984 (PA0046/040/001). Fucibet 20 mg/g + 1 mg/g Cream (MAH: LEO Laboratories Ltd) is a well-known medicinal product with a proven chemical-pharmaceutical quality and an established favourable efficacy and safety profile.

Therapeutic equivalence has been shown to be in compliance with guidance documents. The SmPC is consistent with that of the reference product.

The MAH has provided written confirmation that systems and services are in place to ensure compliance with their pharmacovigilance obligations.

The HPRA, on the basis of the data submitted, considered that Fusidic acid/Betamethasone Laboratoires Medgen 20 mg/g + 1 mg/g Cream demonstrated therapeutic equivalence with the reference product as well as a satisfactory risk/benefit profile and therefore granted a marketing authorisation.

VI. REVISION DATE

05.08.2030