Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Finovare 20 mg/g Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains 20 mg fusidic acid.

Excipient(s) with known effect
Contains cetyl alcohol 111 mg/g, butylhydroxyanisole 0.04 mg/g and potassium sorbate 2.7 mg/g.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
A white cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Topical antibiotic treatment of infections, including impetigo, caused by sensitive micro-organisms, in particular *Staphylococcus aureus*.

Official (local) guidance regarding the correct use of antibacterial agents should be considered.

4.2 Posology and method of administration

Posology

Apply three times daily or as required.
Less frequent application may be adequate for skin covered by a sterile dressing.

Method of administration

Cutaneous use.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Bacterial resistance among *Staphylococcus aureus* has been reported to occur with the use of topical fusidic acid. As with all antibiotics, extended or recurrent use of fusidic acid may increase the risk of developing antibiotic resistance.

Finovare cream contains cetyl alcohol, butylhydroxyanisole and potassium sorbate which may cause local skin reactions such as contact dermatitis. Butylhydroxyanisole may also cause irritation to the eyes and mucous membranes. If used on the face, care should be taken to avoid contact with the eyes.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed. There are no known interactions with other topical or systemic drugs. Systemic absorption of topical fusidic acid is negligible, consequently likelihood of interactions is considered minimal.

4.6 Fertility, pregnancy and lactation

Pregnancy
No effects during pregnancy are anticipated, since systemic exposure to topically applied fusidic acid is negligible. Topical Finovare can be used during pregnancy.

Breast-feeding
It is known that fusidic acid transfers into breast milk. However, the quantities absorbed after topical use are low and are not expected to affect the infant. Finovare can be used during breast-feeding but it is recommended to avoid applying topical Finovare directly on the breast.

Fertility
There are no clinical studies with topical Finovare regarding fertility. No effects in women of childbearing potential are anticipated, since systemic exposure following topically applied fusidic acid is negligible.

4.7 Effects on ability to drive and use machines

Topical administration of Finovare has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Undesirable effects are categorised by frequency as follows:

Very common ≥1/10
Common ≥1/100 to <1/10
Uncommon ≥1/1,000 to <1/100
Rare ≥1/10,000 to <1/1,000
Very rare <1/10,000

Immune system disorders
Rare:
Hypersensitivity

Eye disorders
Rare:
Conjunctivitis

Skin and subcutaneous tissue disorders
Uncommon:
Dermatitis (including dermatitis contact, eczema)
Rash*
Pruritus
Erythema
* *Various types of rash reactions such as erythematous, pustular, vesicular, maculo-papular and popular have been reported. Rash generalised has also occurred.*

Rare:
Angioedema
Urticaria
Blister

General disorders and administration site conditions
Uncommon:
Application site pain (including skin burning sensation)
Application site irritation

Paediatric population
Frequency, type and severity of adverse reactions in children are expected to be the same as in adults.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Website: www.hpra.ie

4.9 Overdose

Overdose is unlikely to occur.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other antibiotics for topical use, ATC code: D06AX01

Finovare cream contains fusidic acid, a potent topical antibacterial. 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. Topical Finovare is also active against Streptococci, Corynebacteria, Neisseria and certain Clostridia.

In a multicentre, Phase 3 randomised, double-blind, two-arm, parallel group clinical study against fusidic acid reference product in a total of 176 patients, Finovare was shown to have equivalent efficacy in the treatment of localised impetigo in adults and children aged 18 months and older.

Susceptibility testing breakpoints
MIC (minimum inhibitory concentration) interpretive criteria for susceptibility testing have been established by the European Committee on Antimicrobial Susceptibility Testing (EUCAST) for fusidic acid and are listed here: https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx.

5.2 Pharmacokinetic properties

There are no data which define the pharmacokinetics of Finovare cream, following topical administration in man.

However, *in vitro* studies show that fusidic acid can penetrate intact human skin in concentrations well above the MIC-values of susceptible organisms. 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.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetyl alcohol
White soft paraffin
Liquid paraffin
Glycerol 85%
Butylhydroxyanisole E320

Polysorbate 60
Potassium sorbate E202
Purified water
Hydrochloric acid

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.
After first opening: use within 1 month.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Internally coated aluminium tube with an HDPE screw cap, placed in a carton box,

Contents: 15 g or 30 g cream.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Citrine Healthcare Limited
Orchard Road
Clondalkin
Dublin 22
D22 V4H1
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23214/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st March 2023

10 DATE OF REVISION OF THE TEXT

October 2025