Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g cream contains 20 mg fusidic acid and 1 mg betamethasone (corresponding to 1.214 mg betamethasone valerate).

Excipients with known effect: contains cetostearyl alcohol 72 mg/g and chlorocresol 1 mg/g.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.

White to off white, smooth, homogeneous cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Use in inflammatory dermatoses where bacterial infection (see section 5.1) is present or likely to occur.

Fusidic acid/Betamethasone Laboratoires 20 mg/g + 1 mg/g cream is indicated in adults and children over 1 year.

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

4.2 Posology and method of administration

Posology
Apply a small quantity to the affected area twice daily until a satisfactory response is obtained. A single treatment course should not normally exceed 2 weeks.

Paediatric population
Fusidic acid/Betamethasone Laboratoires 20 mg/g + 1 mg/g cream is contraindicated in children aged under 1 year (see section 4.3).

Method of administration
For cutaneous use.
A small quantity should be applied thinly to the affected area twice daily until a satisfactory response is obtained.

4.3 Contraindications

Hypersensitivity to the fusidic acid or betamethasone or to any of the excipients listed in section 6.1.

Due to the content of corticosteroid, Fusidic acid/Betamethasone Laboratoires 20 mg/g + 1mg/g cream is contraindicated in the following conditions:

- Infants under one year of age
- Systemic fungal infections
- Primary skin infections caused by fungi, virus or bacteria, either untreated or uncontrolled by appropriate treatment (see section 4.4)
- Skin manifestations in relation to tuberculosis or syphilis, either untreated or uncontrolled by appropriate therapy
- Acne vulgaris.
- Perioral dermatitis and rosacea.

4.4 Special warnings and precautions for use

Systemic absorption
Long-term continuous topical therapy with Fusidic acid/Betamethasone Laboratoires 20 mg/g + 1mg/g cream should be avoided. Depending on the application site, possible systemic absorption of betamethasone valerate should always be considered during treatment with Fusidic acid/Betamethasone Laboratoires 20 mg/g + 1mg/g cream.

Avoid large amounts, occlusion and prolonged treatment (see section 4.8).

Contact with open wounds and mucous membranes should be avoided.

Due to the presence of a corticosteroid, Fusidic acid/Betamethasone Laboratoires should be avoided in: cutaneous ulcers, vulnerable skin veins and perianal and genital pruritus.

Local ocular effects
Due to the content of corticosteroid, Fusidic acid/Betamethasone Laboratoires 20 mg/g + 1mg/g cream should be used with care near the eyes. Avoid getting Fusidic acid/Betamethasone Laboratoires 20 mg/g + 1mg/g cream into the eyes (see section 4.8).
Glaucoma might result if the preparation enters the eye.
Raised intra-ocular pressure and glaucoma may also occur after topical use of steroids near the eyes, particularly with prolonged use in patients predisposed to developing glaucoma.

Visual disturbances
Visual disturbances may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Adrenal suppression
Reversible hypothalamic-pituitary-adrenal (HPA) axis suppression may occur following systemic absorption of topical corticosteroids.

Fusidic acid/Betamethasone Laboratoires 20 mg/g + 1mg/g cream should be used with care in children as paediatric patients may demonstrate greater susceptibility to topical corticosteroids-induced HPA axis suppression and Cushing's syndrome than adult patients.

Cutaneous reactions
Fusidic acid/Betamethasone Laboratoires should be used with caution on large skin areas, on the face and in skin folds.

Atrophic changes may occur on the face and to a lesser degree in other parts of the body, after prolonged treatment with potent topical steroids.

Corticosteroids delay cicatrization.

Risk of topical steroids withdrawal reactions
Long term continuous or inappropriate use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and/or burning sensation itching, skin desquamation and oozing pustules that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated, and may be seen in the event of sudden discontinuation after long-term use. This can be minimised by withdrawing treatment gradually or by substituting a less potent corticosteroid.
Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected.
Reapplication should be with caution and specialist advise is recommended in these cases or other treatment options should be considered, if appropriate.

Bacterial resistance

Bacterial resistance has been reported to occur with the topical use of fusidic acid. As with all antibiotics, extended or recurrent use of fusidic acid may increase the risk of developing antibiotic resistance. Limiting therapy with topical fusidic acid and betamethasone valerate to no more than 14 days at a time will minimize the risk of developing resistance.
This also prevents the risk that the immunosuppressive action of corticosteroid might mask any potential symptoms of infections due to antibiotic-resistant bacteria.
Due to the content of corticosteroid having immunosuppressant effect, Fusidic acid/Betamethasone Laboratoires 20 mg/g + 1mg/g cream may be associated with increased susceptibility to infection, aggravation of existing infection, and activation of latent infection. It is advised to switch to systemic treatment if infection cannot be controlled with topical treatment (see section 4.3).

Excipients with known effects
Fusidic acid/Betamethasone Laboratoires 20 mg/g + 1mg/g cream contains cetostearyl alcohol and chlorocresol as excipients. Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis) and chlorocresol may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy
Fusidic acid:
No effects during pregnancy are anticipated, since systemic exposure to fusidic acid is negligible and studies in animals have not shown teratogenic effects.
Betamethasone valerate:
There are no or limited amount of data from the use of topical betamethasone valerate in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3).

Fusidic acid/Betamethasone Laboratoires 20 mg/g + 1mg/g cream should not be used during pregnancy unless clearly necessary.

Breast-feeding
No effects on the breastfed newborn/infant are anticipated since the systemic exposure of topically applied fusidic acid and betamethasone valerate to a limited area of skin of the breastfeeding woman is negligible. Fusidic acid/Betamethasone Laboratoires 20 mg/g + 1mg/g cream can be used during breast-feeding, but it is recommended to avoid applying Fusidic acid/Betamethasone Laboratoires 20 mg/g + 1mg/g cream on the breast.

Fertility
There are no clinical studies with Fusidic acid/Betamethasone Laboratoires 20 mg/g + 1mg/g cream regarding fertility.

4.7 Effects on ability to drive and use machines

Fusidic acid/Betamethasone Laboratoires 20 mg/g + 1mg/g cream has no or negligible influence on the ability to drive and to use machines.

4.8 Undesirable effects

The estimation of the frequency of undesirable effects is based on a pooled analysis of data from clinical studies and spontaneous reporting.

The most frequently reported adverse reaction during treatment is pruritus.

Undesirable effects are listed by MedDRA SOC and the individual undesirable effects are listed starting with the most frequently reported. Within each frequency grouping, adverse reactions are presented in the order of decreasing seriousness.

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

Very rare <1/10,000
Not known (cannot be estimated from the available data).

Immune system disorders	
Uncommon:	Hypersensitivity*
Eye disorders	
Not known:	Vision blurred (see section 4.4)
Skin and subcutaneous tissue disorders	
Uncommon:	Contact dermatitis* Eczema (condition aggravated) Skin burning sensation Pruritus Dry skin
Rare:	Erythema Urticaria Rash (including rash erythematous and rash generalised)
Not known	Topical steroid withdrawal reaction**
General disorders and administration site conditions	
Uncommon:	Application site pain Application site irritation
Rare:	Application site vesicles Application site swelling

* The frequency is estimated by post marketing experience
** Topical steroid withdrawal reactions: reactions related to prolonged or inappropriate use, which may extend beyond the initially treated area (redness of the skin, burning and/or tingling sensation, itching, skin desquamation, oozing pustules).

Systemic undesirable class effects of corticosteroids like betamethasone valerate include adrenal suppression especially during prolonged topical administration (see section 4.4).

Dermatological undesirable class effects of potent corticosteroids include: Atrophy, dermatitis (incl. contact dermatitis and acneiform dermatitis), perioral dermatitis, skin striae, telangiectasia, rosacea, erythema, hypertrichosis, hyperhidrosis, and depigmentation.

Ecchymosis may also occur with prolonged use of topical corticosteroids. Class effects for corticosteroids have been uncommonly reported for Fusidic acid/Betamethasone Laboratoires 20 mg/g + 1mg/g cream as described in the frequency table above.

Paediatricpopulation
Compared with adults, children are at higher risk for the local and systemic side effects of topical corticosteroids (see section 4.4).

Reportingofsuspectedadversereactions
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

For topically applied fusidic acid, no information concerning potential symptoms and signs due to administration of an overdose is available. Cushing's syndrome and adrenocortical insufficiency may develop following topical application of corticosteroids in large amounts and for more than three weeks.
Systemic consequences of an overdose of the active substances after accidental oral intake are unlikely to occur. The amount of fusidic acid in one tube of Fusidic acid/Betamethasone Laboratoires 20 mg/g + 1mg/g cream does not exceed the oral daily dose of systemic treatment. A single oral overdose of corticosteroids is rarely a clinical problem.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Fusidic acid/Betamethasone Laboratoires 20 mg/g + 1mg/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.

Resistance
Two main types of resistance mechanisms have been characterized in S. aureus. The first is caused by mutations in the fusidic acid binding site of EF-G (fusA) and the other involves horizontal acquisition of determinants encoding the FusB-type resistance determinants (fusB and fusC) that bind to EF-G.

Due to the unique molecular structure and distinct mode of action of fusidic acid, target specific cross resistance with other classes of antibacterial agents has not been detected.

Susceptibility testing breakpoints
Susceptibility test breakpoints relevant for the cutaneous administered fusidic acid cannot be set and no clinical breakpoints exist.
The epidemiological breakpoint (ECOFF) for fusidic acid has been set by the European Committee on Antimicrobial Susceptibility (EUCAST) for some of the susceptible species and are listed:
<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>.

The prevalence of acquired resistance can vary according to geography and time for certain species. It is therefore useful to have information on the prevalence of local resistance, particularly for the treatment of severe infections. Such data can only give an indication of the likelihood of a bacterial strain being susceptible to that antibiotic.

5.2 Pharmacokinetic properties

There are no data which define the pharmacokinetics of Fusidic acid/Betamethasone Laboratoires 20 mg/g + 1mg/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.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and carcinogenic potential.

Studies of corticosteroids in animals have shown reproductive toxicity (e.g. cleft palate, skeletal malformations, low birth weight).

Environmental risk assessment studies have shown that betamethasone may pose a risk for the aquatic compartment.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol cetostearyl ether
Cetostearyl alcohol
Chlorocresol
Liquid paraffin
Sodium dihydrogen phosphate dihydrate
White soft paraffin
All-rac-α-tocopherol
Purified water
Sodium hydroxide (for pH adjustment)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened container: 3 years.
After first opening of container: 6 months.

6.5 Nature and contents of container

Internally lacquered aluminium tubes with foreseal and a white conical polyethylene cap, containing either 5 grams, 15 grams, 30 grams, and 60 grams of cream.
Pack size: 1 tube of 5 g, 15 g, 30 g or 60 g.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

This medicinal product may pose a risk to the environment. (See section 5.3).

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

7 MARKETING AUTHORISATION HOLDER

Laboratoires Medgen
24 Rue Erlanger
Paris
75016
France

8 MARKETING AUTHORISATION NUMBER

PA25250/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 12th September 2025

10 DATE OF REVISION OF THE TEXT