SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
FUSIX DERMACORT 2% + 0.1% cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each gram of cream contains:
Active substances:
Fusidic acid (produced from bovine milk powder) 20 mg
Betamethasone valerate 1.214 mg (equivalent to 1 mg of betamethasone)

Excipients:
Cetostearyl alcohol 72 mg
Chlorocresol 1 mg
For excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Cream
A white or off-white, soft-textured, homogeneous cream

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
FUSIX DERMACORT is indicated for inflammatory dermatoses with an existing or potential bacterial infection. Inflammatory dermatoses include atopic eczema, discoid eczema, stasis eczema, seborrheic dermatitis, contact dermatitis, chronic lichen simplex, psoriasis, and discoid lupus erythematosus.

4.2 Posology and method of administration
Posology/frequency and duration of administration:
Applied to the lesions 2 or 3 times daily.

Method of administration:
It is applied externally on the skin surface.
FUSIX DERMACORT treatment should be discontinued as soon as the condition improves. Treatment should not exceed 2weeks without reassessment.

Additional information on special populations:
Renal/Hepatic impairment:
No dose adjustment is necessary for renal impairment.

Since betamethasone is metabolized in the liver, caution should be exercised in patients with hepatic impairment.

Pediatric population:
The use of topical corticosteroid-containing medications in children should be limited to the lowest amount necessary to achieve effective treatment.

FUSIX DERMACORT should not be used for the treatment of nappy rash in infants.

In the pediatric age group, it is not recommended unless absolutely necessary.

Geriatric population:
There is no data regarding its use in elderly patients.

4.3 Contraindications

It should not be used in case of hypersensitivity to fusidic acid or betamethasone valerate or any of the excipients.

FUSIX DERMACORT is contraindicated in the following cases due to the corticosteroid content:

- Systemic fungal infections
- Primary skin infections caused by fungi, viruses or bacteria that are untreated or can not controlled by appropriate treatment (see section 4.4)
- Skin findings associated with tuberculosis that are untreated or can not controlled by appropriate treatment
- Rosacea, acne vulgaris, perioral dermatitis and skin ulceration
- Skin diseases in children under 1 year of age, including dermatitis and diaper dermatitis

4.4 Special warnings and precautions for use

Prolonged and continuous topical treatment with corticosteroids, especially on the face, in creased areas, and in children, should be avoided whenever possible, as they may lead to adrenal suppression even in the absence of occlusion therapy.

During treatment with FUSIX DERMACORT, the possible systemic absorption of betamethasone valerate must always be taken into account, depending on the application area.

Since FUSIX DERMACORT contains corticosteroids, caution should be exercised when used in areas close to the eyes. FUSIX DERMACORT should be avoided from contact with the eyes (see section 4.8).

Visual disturbances may be reported with systemic and topical use of corticosteroids. If patients develop symptoms such as blurred vision or other visual disturbances, consultation with an ophthalmologist may be considered to evaluate the possibility of a cause of rare diseases such as cataract, glaucoma, or central serous chorioretinopathy, which have been reported after systemic or topical corticosteroid use.

Reversible hypothalamic-pituitary-adrenal (HPA) axis suppression may occur due to systemic absorption of topical corticosteroids. FUSIX DERMACORT should be used with caution in children because pediatric patients are more sensitive to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome.

High amounts, occlusive and long-term treatments should be avoided (see section 4.8).

Since FUSİX DERMACORT contains betamethasone valerate, long-term topical use may cause skin atrophy on the face, genital areas, inner surfaces of the arms and legs, and less frequently in other parts of the body.

In cases of perianal or genital itching, FUSİX DERMACORT should be used only for a short

duration.

Development of bacterial resistance has been reported with topical use of fusidic acid. The risk of developing bacterial resistance may increase with prolonged or frequent use of fusidic acid. Not using fusidic acid and betamethasone valerate treatment for more than 14 days minimizes the risk of bacterial resistance development. This use also avoids the potential risk of suppressing symptoms of infections caused by antibiotic-resistant bacteria due to the immunosuppressive effects of corticosteroids.

FUSİX DERMACORT may be associated with increased susceptibility to infection, exacerbation of existing infection and exacerbation of latent infection, due to the immunosuppression effect caused by its corticosteroid content.

In infections that cannot be controlled by topical treatments, it is recommended to combine it with a systemic treatment (see section 4.3).

This medicinal product contains cetostearyl alcohol and chlorocresol. Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis). Chlorocresol may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interactionş

No drug interaction studies have been conducted. Its interaction with systemically administered drugs is thought to be minimal.

4.6 Fertility, pregnancy and lactation

General recommendation

Pregnancy category: C.

Women of childbearing potential / Birth control (Contraception)

There is no information regarding the use in women of childbearing potential or those using contraception.

Pregnancy

Fusidic acid:

Since the amount passing into systemic circulation is negligible, there is no expected side effect during pregnancy.

Betamethasone valerate:

There is limited or insufficient data on betamethasone valerate in pregnant women. Animal studies have shown that it has an effect on reproduction (see section 5.3).

FUSIX DERMACORT should not be used during pregnancy unless there is a clinical condition requiring treatment with in women.

Lactation

Since the systemic effects of fusidic acid and betamethasone valerate applied to the skin are negligible due to their use in limited areas in breastfeeding mothers, no effect is expected in breastfed newborns/infants.

FUSIX DERMACORT can be used during breastfeeding, but it is not recommended to apply FUSIX DERMACORT to the breast.

Reproductive ability/Fertility
There are no clinical studies on fertility with fusidic acid and betamethasone valerate.

4.7 Effects on ability to drive and use machines
FUSIX DERMACORT has no or negligible effect on driving and using machines.

4.8 Undesirable effects
Estimated frequency of adverse reactions; based on an analysis of data collected from clinical studies and spontaneous reporting.

The most commonly reported side effect during treatment is pruritus.

Adverse reactions considered to be related to the drug are listed below:

Frequencies are defined 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); not known (cannot be estimated from the available data).

Immune system disorders
Uncommon: Hypersensitivity

Eye disorders
Not known: Blurred vision (see section 4.4)

Skin and subcutaneous tissue disorders
Uncommon: Exacerbation of eczema, urticaria, contact dermatitis, pruritus, dry skin, burning sensation on the skin.
Rare: Erythema, urticaria, rash (including erythematous rash and generalized rash**)**

General disorders and diseases related to the application area
Uncommon: Pain and irritation at the application site
Rare: Swelling and vesicle formation at the application site

Systemic adverse class effects of corticosteroids such as betamethasone valerate include adrenal suppression, particularly during prolonged topical application (see section 4.4).

Intraocular use of topical corticosteroids may result in increased intraocular pressure and glaucoma, especially with prolonged use and in patients predisposed to glaucoma (see section 4.4).

Dermatologic adverse effects of potent corticosteroids include: Atrophy, dermatitis (including contact dermatitis and acneiform dermatitis), telangiectasia and skin cracks, hypertrichosis, perioral dermatitis, rosacea, erythema, hyperhidrosis, and depigmentation.
Ecchymosis may also occur with long-term use of topical corticosteroids.

Class effects observed for corticosteroids have been reported uncommonly for betamethasone valerate as described above.

Paediatric population:
The observed safety profile is similar in children and adults (see section 4.4).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization 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 the national reporting system.

4.9 Overdose
For topically applied fusidic acid, no information is available regarding possible symptoms and signs associated with overdosage. Cushing's syndrome and adrenocortical insufficiency may develop following topical application of high amounts of corticosteroids for more than three weeks.

It is unlikely that systemic consequences of overdose of active substances will occur after accidental oral ingestion. The amount of fusidic acid in one tube of FUSIX DERMACORT does not exceed the oral daily systemic treatment dose. A clinical problem rarely occurs with a single oral overdose of corticosteroids.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic Group: Corticosteroids, potent (combinations with antibiotics)
ATC Code: D07CC01

FUSIX DERMACORT is a combination of betamethasone valerate, which has well-known anti-inflammatory and antipruritic effects, and fusidic acid, a topical antibacterial agent.

Fusidic acid is primarily active against Gram-positive bacteria and is particularly very effective against *Staphylococcus aureus, Propionibacterium acnes,* and *Corynebacterium* species. It is effective against microorganisms resistant to penicillins and other antibacterials. Almost all strains of *S. aureus* are inhibited at concentrations of 0.03-0.12 mcg/ml. Betamethasone valerate belongs to the potent corticosteroid group and when applied locally, it acts by suppressing local immune reactions such as vasodilation, swelling and pain.

When applied topically, the antibacterial effect of fusidic acid is not reduced by the presence of betamethasone.

5.2 Pharmacokinetic properties
General characteristics
There is no available data describing the pharmacokinetic properties of FUSIX DERMACORT in humans.

Absorption:
Betamethasone is absorbed following topical application to inflamed skin. The degree of absorption depends on various factors such as skin condition and route of application. The systemic penetration of fusidic acid through intact human skin is negligible.

Distribution:
There is no available data on the distribution of FUSIX DERMACORT.

Biotransformation:
Betamethasone is largely metabolized in the liver and to a lesser extent in the kidneys. Fusidic acid undergoes extensive metabolism in the liver.

Elimination:
Betamethasone is excreted in the urine as inactive metabolites.

Fusidic acid is primarily excreted via bile and, to a lesser extent, in urine.

5.3 Preclinical safety data
Corticosteroid studies in animals have shown reproductive toxicity (e.g. cleft palate, skeletal malformations, low birth weight).

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Cetostearyl alcohol
Macrogol cetostearyl ether
Chlorocresol
Sodium dihydrogen phosphate dihydrate
Liquid paraffin
White soft paraffin
Sodium hydroxide
Deionized water

6.2 Incompatibilities
Not reported.

6.3 Shelf life
24 months

6.4 Special precautions for storage
Store at room temperature below 25°C.

6.5 Nature and contents of container
The primary packaging material is an aluminum tube with a white HDPE screw cap.

Available in 30 g tubes. Each box contains one tube and a package leaflet.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORIZATION HOLDER
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8. MARKETING AUTHORISATION NUMBER(S)

2018/86

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:19.02.2018
Date of latest renewal:

10. DATE OF REVISION OF THE SPC

28.02.2025