SUMMARY OF PRODUCT CHARACTERISTICS

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1. Name of the medicinal product

Topidic® (Fusidic acid 2%) Cream

2. Qualitative and quantitative composition

Topidic® Cream contains Fusidic acid 20mg/1gm.
For a full list of excipients, see section 6.1

3. Pharmaceutical form

Cream for topical administration

Topidic® is white cream, packed in cylindrical collapsible aluminum tubes, intended for topical use.

4. Clinical particulars

4.1 Therapeutic indications

Topidic® cream is indicated either alone or in combination with systemic therapy, in the treatment of primary and secondary skin infections caused by sensitive strains of *Staphylococcus aureus,* Streptococcus spp and *Corynebacterium minutissimum*. Primary skin infections that may be expected to respond to treatment with fusidic acid applied topically include: impetigo contagiosa, superficial folliculitis, sycosis barbae, paronychia and erythrasma; also such secondary skin infections as infected eczematoid dermatitis, infected contact dermatitis and infected cuts/abrasions..

4.2 Posology and method of administration

Adults and Children:
Uncovered lesions - apply gently three or four times daily.
Covered lesions - less frequent applications may be adequate

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 **Topidic® cream**. As with all antibiotics, extended or recurrent use may increase the risk of developing antibiotic resistance.
Extended or recurrent use may increase the risk of developing contact sensitization.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed. Interactions with systemically

administered medicinal products are considered minimal as the systemic absorption of topical **Topidic® cream** is negligible.

4.6 Fertility, pregnancy and lactation

Fertility

There are no clinical studies with topical **Topidic® cream** regarding fertility. No effects in women of childbearing potential are anticipated, since systemic exposure following topically applied fusidic acid/sodium fusidate is negligible.

Pregnancy

No effects during pregnancy are anticipated, since systemic exposure to topically applied fusidic acid/sodium fusidate is negligible. **Topidic® cream** can be used during pregnancy.

Breast-feeding

No effects on the breastfed new-born/infant are anticipated since the systemic exposure of topically applied fusidic acid/sodium fusidate to the breast-feeding woman is negligible. **Topidic® cream** can be used during breast-feeding but it is recommended to avoid applying **Topidic® cream** on the breast.

4.7 Effects on ability to drive and use machines

Topidic® cream administered topically has no or negligible influence on the ability to drive or 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 trials and from spontaneous reporting.

Based on pooled data from clinical studies including 4724 patients who received **Topidic® cream** or **Topidic® ointment**, the frequency of undesirable effects is 2.3%.

The most frequently reported adverse reactions during treatment are various skin reactions such as pruritus and rash, followed by application site conditions such as pain and irritation, which all occurred in less than 1% of patients.

Hypersensitivity and angioedema have been reported.

Undesirable effects are listed by MedDRA System Organ Class (SOC) and the individual undesirable effects are listed starting with the most frequently reported. Within each frequency grouping, adverse reactions are presented in 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

Immune system disorders

Rare

(≥1/10,000 and <1/1,000)
Hypersensitivity

Eye disorders

Rare
(≥1/10,000 and <1/1,000)
Conjunctivitis

Skin and subcutaneous tissue disorders

Uncommon
(≥1/1,000 and <1/100)
Dermatitis (incl. dermatitis contact, eczema)
Rash*
Pruritus
Erythema
*Various types of rash reactions such as erythematous, pustular, vesicular, maculo-papular and papular have been reported. Rash generalised has also occurred.
Rare
(≥1/10,000 and <1/1,000)
Angioedema
Urticaria
Blister

General disorders and administration site conditions

Uncommon
(≥1/1,000 and <1/100)
Application site pain (incl. 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.

4.9 Overdose

Overdose is unlikely to occur
Unless hypersensitivity to Fusidic acid or any of the excipients exists, accidental ingestion of **Topidic® cream** is unlikely to cause any harm. The total quantity of fusidic acid (30 g **Topidic® cream** contains 600 mg fusidic acid) will usually not exceed the approved total daily oral dose of fusidic acid containing products except in children aged less than 1 year and weighing ≤ 10 kg. Although in this instance a child of this particular age group is unlikely to ingest a whole tube of **Topidic® cream**. The concentration of the excipients is too low to constitute a safety risk.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Fusidic acid is a potent antibacterial agent. Fusidic acid and its salts show fat

and water solubility and strong surface activity and exhibit unusual ability to penetrate intact skin. Concentrations of 0.03 - 0.12 mcg fusidic acid per ml inhibit nearly all strains of *Staphylococcus aureus.* Topical application of fusidic acid is also effective against streptococci, corynebacteria, neisseria and certain clostridia.

5.2 Pharmacokinetic properties

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.

5.3 Preclinical safety data

There are no pre-clinical 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

Light mineral oil, white petrolatum, cetostearyl alcohol, macrogol cetostearyl ether cetomacrogol, propyl paraben, methyl paraben, tri-sodium citrate di-hydrate, citric acid.1H_2O, propylene glycol .

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

After opening:
Discard after 20 days from opening the tube.

6.4 Special precautions for storage

Store below 25°C before & after opening of the tube.

6.5 Nature and contents of container

Topidic® cream is packed in Cylindrical Collapsible aluminum tubes of high resistance to cold & elasticity as primary packaging material and packed in cartoon box as secondary packaging material.
Pack size: 15gm

6.6 Special precautions for disposal and other handling

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

Discard after 20 days from opening of the tube.

7. Marketing authorization holder

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8. Marketing authorisation number(s)

Registration Number:
04380/06778/REN/2018

9. Date of first authorisation/renewal of the authorization

Registration Date: Apr 5, 2019

10. Date of revision of the text

07/2018