SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product

1.1 Product name: TOSIDIC

1.2 Strength: 2 % Fusidic acid

1.3 Pharmaceutical dosage form: Cream

2. Qualitative and quantitative composition

TOSIDIC cream contains Fusidic acid hemihydrate 20.35 mg equivalent to anhydrous Fusidic acid 20 mg/g.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Cream for topical administration.

A white cream.

4. Clinical particulars

4.1 Therapeutic indications

TOSIDIC 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

Posology

Adults and Paediatric population

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 TOSIDIC. 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 sensitisation.

TOSIDIC cream contains butylated hydroxyanisole, cetyl alcohol and polysorbate. These excipients may cause local skin reactions (e.g. contact dermatitis). Butylated hydroxyanisole may also cause irritation to the eyes and mucous membranes. TOSIDIC cream should therefore be used with care when applied in the proximity of the eyes.

Instruct patients not to smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc.) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

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 TOSIDIC is negligible.

4.6 Fertility, pregnancy and lactation

Pregnancy

No effects during pregnancy are anticipated, since systemic exposure to topically-applied fusidic acid/sodium fusidate is negligible. Topical TOSIDIC can be used during pregnancy.

Breast-feeding

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

Fertility

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

4.7 Effects on ability to drive and use machines

TOSIDIC administered topically has no or negligible influence on the ability to drive and 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 4,724 patients who received Fusidic acid cream, 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 (including 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 (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 electronic submission of ICSRs using the HPVC adverse event reporting system https://hpvcthai.fda.moph.go.th , https://privus.fda.moph.go.th/ primarily required for all MAHs. Additional information should be provided in the attachment to the system, if applicable. MAHs use e-mail or mail for reporting only (adr@fda.moph.go.th) when HPVC adverse events system access is unavailable.

4.9 Overdose

Overdose is unlikely to occur

Unless hypersensitivity to Fusidic acid or any of the excipients exists, accidental ingestion of TOSIDIC cream is unlikely to cause any harm. The total quantity of fusidic acid (30 g TOSIDIC 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 TOSIDIC cream. The concentration of the excipients is too low to constitute a safety risk.

5. Pharmacological properties

5.1 Pharmacodynamic properties

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

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

I*n 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

White soft paraffin
Light liquid paraffin
Cetyl alcohol
Butylated hydroxyanisole
Sorbitan stearate
Polysorbate 60
Edetate disodium
Sodium citrate dehydrate
Anhydrous Citric acid
Methylparaben
Propylparaben
Propylene glycol
Glycerin
Purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

None.

6.5 Nature and contents of container

Aluminium tubes of 5 g.

6.6 Special precautions for disposal and other handling

None.

7. Marketing authorisation holder

T.O. Chemicals (1979) Limited

280 Soi Sabaijai, Suthisarnwinijai Road,

Samsennok, Huay-Kwang, Bangkok 10310, Thailand

8. Marketing authorization number

1A 128/67

9. Date of first authorization/renewal of the authorization

17 December 2024 / 16 December 2031

10. Date of revision of the text

11 November 2024