SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF MEDICAL PRODUCT

TIREMIX 2 % Cream

2. QUANTITATIVE AND QUALITATIVE COMPOSITION

Active Ingredient

Fucidic acid	20 mg/g

Excipients

Butyl hydroxy anisole	0,04 mg/g
Cetyl alcohol	111 mg/g

For excipients see section 6.1.

3. PHARMACEUTYCAL FORM

Cream

4. CLINICAL FEATURES

4.1 Theraputıc Indıcations

TIREMIX is indicated for staphylococci, streptococci, propionibacterium acnes, corynebacterium minutissimum and other TIREMIX-sensitive organisms.
The major indications for these indications are infected burns and wounds, impetigo, infected eczema, folliculitis, infected acne, abscess, acne vulgaris, paronychia, cycosis barbae, hydrozadenitis and erythrasmia.

4.2 Posology and application form

Posology/frequency and duration of administration

It is applied to the lesions 2-3 times a day and is recommended by the doctor. Can be coated or left open after application.

Application form

Applied externally on the skin.

Additional Information For Special Populations

Kidney/Liver Failure

There is no study with fusidic acid used topically in renal and hepatic failure

Pediatric Population

There is no use restriction in pediatric patients.

Geriatric Population
There is no use restriction in geriatric patients.

4.3 Contraindications
Contraindicated in case of hypersensitivity to fusidic acid and its salts or any of the other components. It should not be used for infections caused by insensitive organisms such as *Pseudomonas aeruginosa*.

4.4 Special warnings and precautions for use
Avoid eye contact as it may cause eye irritation.
As with all other topical antibiotics, prolonged and frequent administration may increase the risk of contact sensitivity and the development of resistance to antibiotics.

4.5 Interactions with other medicinal products and other forms of interaction
No interaction was observed with other drugs.

4.6 Pregnancy and Lactation

General advice

Pregnancy
Pregnancy category is B.

Women with childbearing potential / Birth Control (Contraception)
Studies on animals do not show any direct or indirect detrimental effects in relation to pregnancy / embryonal / fetal development / birth or postnatal development. Care should be taken when administering to pregnant women.

Lactation
It is not known whether fusidic acid is excreted in human milk. However, the benefit / harm relationship should be used with the condition that the physician evaluates in detail..

Fertility
The effect on reproductive ability is unknown.

4.7 Effects on ability to drive and use machines
No adverse effects were reported on vehicle and machine use.

4.8 Undesirable effects
Very common (≥1/10); common (≥1/100 ila <1/10); Uncommon (≥1/1.000 ila <1/100); rare (≥1/10.000 ila <1/1.000); Very rare (<1/10.000), Unknown

Disorders of the immune system
Unknown: Allergic reaction

Dermatological disorders
Uncommon: Exanthema skin irritation, itching, burning and stinging sensation, erythema, dry skin.

Unknown: Contact dermatitis, eczema, urticaria, angioneurotic edema.

4.9 Overdose and treatment
There is no information that overdose may occur in local administration with fusidic acid.

5. PHARMACOLOGYCAL FEATURES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Other antibiotics used topically
ATC Code: D06AX01

Fusidic acid, the active ingredient of TIREMIX; Fucudium is an antibiotic obtained from cuccineum culture and has a strong antibacterial effect on many gram-positive organisms.

Fusidic acid inhibits bacterial protein synthesis by inhibiting amino acid transfer from aminoacyl-sRNA to proteins in ribosomes.

Staphylococci that are resistant to penicillin or other antibiotics are particularly sensitive to TIREMIX.

The therapeutic efficacy of topically administered TIREMIX is due in part to its antibacterial effect on organisms that cause skin infections, and in part to the ability of this antibiotic to penetrate through the skin of intact integrity.

Pharmacokinetic properties

In-vitro studies have shown 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

Elimination: Fusidic acid is mainly excreted in bile and a small amount in urine.

5.2 Preclinical safety data
Not applicable

6. PHARMACEUTICAL FEATURES

6.1 List of excipients
Cetyl alcohol
White soft paraffin
Polysorbate 60 (E435)
Butyl hydroxy anisole (E320)
Liquid paraffin
Pure water
Glycerol (E422)
Potassium sorbate (E202)
Hydrochloric acid

6.2 Incompatibilities
It does not have any known incompatibilities.

6.3 Shelf life

24 months

6.4 Special precautions for storage
Store at room temperature below 30 ° C, protected from direct sunlight and heat.

6.5 Nature and content of packaging
15 and 20 gram aluminum tube and plastic (HDPE) lid

6.6 Disposal of other medicinal products and other special precautions

Unused products or waste materials should be disposed in accordance with the "Regulation for the Control of Medical Wastes" and the "Regulation for the Control of Packages and Package Wastes".

7. Marketing Authorisation Holder

Humanis Saglik A.S.
Istanbul/Turkey

8. MARKETING AUTHORISATION NUMBER(S)
07610/09540/NMR/2022
09495/08765/VAR/2023

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First License Date: 19.02.2014
License Renewal Date:

10. 10. DATE OF REVISION OF THE TEXT