Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product

Zudic Cream(Fusidic Acid) BP 20mg

2. Qualitative and quantitative composition

Each gram contains Fusidic acid BP ... 20 mg.

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

White colored semisolid cream.

4. Clinical particulars

4.1 Therapeutic indications

Zudic cream is indicated for the treatment of skin infections caused by staphylococci, streptococci,
propionibacterium acnes, corynebacterium minutissimum and other Fusidic acid sensitive organisms. Zudic cream is used in following skin infections:
Infected Wounds Boils, Impetigo Paronychia, Carbuncles Sycosis barbae, Hidradenitis Erythrasma, Folliculitis Acne Vulgaris,
After application Zudic cream is invisible, non-staining which is cosmetically acceptable for treatment of face & scalp infections.

4.2 Posology and method of administration

Zudic cream is applied to the affected area twice or thrice a day usually for a period of 7 days except for acne where therapy can be extended for a long period according to severity of diseases.

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 Zudic. 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.
Zudic cream contains butylhydroxyanisole, cetyl alcohol and potassium sorbate. These excipients may cause local skin reactions (e.g. contact dermatitis). Butylhydroxyanisole may also cause irritation to the eyes and mucous membranes. Zudic cream should therefore be used with care when applied in the proximity of the eyes.

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 Zudic 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 Zudic 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

Fertility

There are no clinical studies with topical Zudic 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.

Zudic 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 4724 patients who received Zudic cream or Zudic 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.

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 the PPB website https://pv.pharmacyboardkenya.org.

4.9 Overdose

Overdose is unlikely to occur

Unless hypersensitivity to Fusidic acid or any of the excipients exists, accidental ingestion of Zudic cream is unlikely to cause any harm. The total quantity of fusidic acid (30 g Zudic 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 Zudic 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

Pharmacokinetics:
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

Methyl Paraben, Propyl Paraben, Benzoic Acid, White Petroleum Jelly, Liquid Paraffin ,Stearic Acid, Cetyl Alcohol, Glyceryl Monostearate, Emulsifying Wax, Lanolin Anhydrous, Glycerin Pure, De-Ionized Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage:

Store below 30°C.
Protect from light and moisture.
Keep out of the reach of children.

6.5 Nature and contents of container

Zudic cream is available in tube of 15 g.

6.6 Special precautions for disposal and other handling:
No special requirements.

7. Marketing authorization holder and manufacturing site addresses

Marketing authorization holder:
Nabiqasim Industries (Pvt.) Ltd.
17/24, Korangi Industrial Area,
Korangi,
Karachi – Pakistan.

Manufacturing site address:
Nabiqasim Industries (Pvt.) Ltd.
17/24, Korangi Industrial Area,
Korangi,
Karachi – Pakistan.

8. Marketing authorization number
H2024/CTD6712/12993

9. Date of first registration
15-02-2024

10. Date of revision of the text:
11/2024