1. Name of the medicinal product
Fusibact cream

2. Qualitative and quantitative composition
Fusibact cream contains Fusidic Acid 20 mg/g.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form
Cream for topical administration.
White to off white smooth cream, free from grit or hard lumps.

4. Clinical particulars
4.1 Therapeutic indications

Fusidic Acid 20 mg/g 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 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 Fusidic Acid. 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.
Fusidic Acid 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. Fusidic Acid 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 Fusidic Acid is negligible.

4.6 Fertility, pregnancy and lactation

Pregnancy
No effects during pregnancy are anticipated, since systemic exposure to topically-applied /sodium fusidate is negligible. Topical Fusidic Acid 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 /sodium fusidate to the breast-feeding woman is negligible. Topical Fusidic Acid can be used during breast-feeding but it is recommended to avoid applying topical Fusidic Acid on the breast.
Fertility
There are no clinical studies with topical Fusidic Acid regarding fertility. No effects in women of childbearing potential are anticipated, since systemic exposure following topically-applied /sodium fusidate is negligible.

4.7 Effects on ability to drive and use machines

Fusidic Acid 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 Fusidic Acid cream or Fusidic Acid 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 (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.

4.9 Overdose

Overdose is unlikely to occur
Unless hypersensitivity to or any of the excipients exists, accidental ingestion of Fusidic Acid cream is unlikely to cause any harm. The total quantity of (30 g Fusidic Acid cream contains 600 mg) will usually not exceed the approved total daily oral dose of 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 Fusidic Acid 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
 is a potent antibacterial agent. 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

per ml inhibit nearly all strains of *Staphylococcus aureus.* Topical application of is also effective against streptococci, corynebacteria, neisseria and certain clostridia.

5.2 Pharmacokinetic properties

In vitro studies show that can penetrate intact human skin. The degree of penetration depends on factors such as the duration of exposure to and the condition of the skin. 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

Butylated Hydroxyanisole
Cetyl Alcohol
Glycerol (Glycerine 100%)
Propylene Glycol
Liquid Paraffin
Simethicone USP (100 %)
Potassium Sorbate
Polysorbate 60 (Tween 60)
Polysorbate 80 (Tween 80)
White Petroleum Jelly
(White Soft Paraffin BP)
Hydrochloric Acid 1N
And / Or
Sodium Hydroxide 1N
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Don’t store above 30°C.

In-use/End of Shelf Life:- Discard after 3 months of opening.

6.5 Nature and contents of container

15 gm of cream is filled in printed Collapsible Aluminum tubes with HDPE cap. One such tube is packed with outer carton and Patient Information Leaflet (PIL).

6.6 Special precautions for disposal and other handling

None.

7. Marketing authorisation holder
JAMJOOM PHARMACEUTICALS COMPANY

Plot No. ME1:3, Phase V, Industrial City,

P.O. Box 6267, Jeddah-21442,

Kingdom of Saudi Arabia

8. Marketing authorisation number(s)
B4-8036

9. Date of first authorisation/renewal of the authorisation
20-Dec-2017

10. Date of revision of the text
19-Oct-2022