Summery of product characteristics:

1. Name of the medicinal product

Fusibact Ointment 15 g

2. Qualitative and quantitative composition

Fusibact Ointment contains Sodium Fusidate 20 mg/g

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Ointment for topical administration.

White to off white homogenous ointment, free from grit or lumps, filled in Aluminum

Collapsible Tube.

4. Clinical particulars

4.1 Therapeutic indications

Sodium Fusidate ointment 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 Sodium Fusidate. 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.

Sodium Fusidate ointment contains cetyl alcohol and hydrous lanolin. These excipients may cause local skin reactions (e.g., contact dermatitis). Sodium Fusidate ointment contains butylhydroxytoluene (E321) which may cause local skin reactions (e.g., contact dermatitis) or irritation to the eyes and mucous membranes.

When Sodium Fusidate ointment is used on the face; care should be taken to avoid the eyes as the excipients in the ointment may cause conjunctival irritation.

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 Sodium Fusidate 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 Sodium Fusidate 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 Sodium Fusidate can be used during breast-feeding, but it is recommended to avoid applying topical Sodium Fusidate on the breast.

Fertility

There are no clinical studies with topical Sodium Fusidate 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

Sodium Fusidate 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 Sodium Fusidate cream or Sodium Fusidate 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 various 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 Fusidic acid or any of the excipients exists, accidental ingestion of Sodium Fusidate ointment is unlikely to cause any harm. The total quantity of fusidic acid (30 g Sodium Fusidate ointment contains 576 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 Sodium Fusidate ointment. 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 topical 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 microgram/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

White Soft Paraffin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

Discard the tube after 3 months from opening.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

15 g of ointment is filled in printed Collapsible Aluminum tubes 15 g with high density Polyethylene (HDPE) caps.with spike for piercing. One such tube is packed in a carton along with one Patient Information Leaflet (PIL).

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

None.

7. Marketing authorisation holder

JAMJOOM PHARMACEUTICALS COMPANY

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P.O. Box 6267

Jeddah-21442

Kingdom of Saudi Arabia

Tel: 00966-12-6081111

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8. Marketing authorisation number(s)

B4-8035

9. Date of first authorization/renewal of the authorization

20-Dec-2017

10. Date of revision of the text

19-Oct-2022