NAME OF THE MEDICINE

Fucidin® ointment.

Fucidin® ointment contains Sodium fusidate. Sodium fusidate is Sodium ent-(17Z)-16α-(acetyloxy)-3β,11β-dihydroxy-4β,8,14-trimethyl-18-nor-5β,10α-cholesta-17(20), 24-dien-21-oate; C₃₁H₄₇NaO₆; a white or almost white crystalline powder, slightly hygroscopic, and freely soluble in water and ethanol (96 per cent). The CAS number is 751-94-0.

**Sodium Fusidate**

\[
\text{C}_{31}\text{H}_{47}\text{NaO}_6 \quad \text{Mw 538.7}
\]

pH 7.5 – 9.0

Partition coefficient: 2.6

pKa: 4.9

DESCRIPTION

Fucidin® ointment is a translucent yellowish to white ointment.

Fucidin® ointment contains sodium fusidate 20 mg/g in a neutral ointment base containing cetyl alcohol, liquid paraffin, white soft paraffin and wool fat.

PHARMACOLOGY

*Fucidin*, an antibiotic derived from Fusidium coccineum, exerts powerful antibacterial activity against a number of gram-positive organisms. Staphylococci, including the strains resistant to penicillin or to other antibiotics, are particularly susceptible to *Fucidin*.

*Fucidin* is highly diffusible, so that active concentrations are found even under crusted areas.
INDICATIONS

Skin lesions primarily and secondarily infected with staphylococci, e.g. abscesses, boils, furunculosis, impetigo, folliculitis, hidradenitis, pyoderma, sycosis barbae, otitis externa.

CONTRAINDICATIONS

Infections caused by non-susceptible organisms. Patients with hypersensitivity to the active substance or any of the excipients.

PRECAUTIONS

When used for the treatment of facial lesions, care must be taken not to introduce ointment into the eyes as the excipients in the ointment may cause conjunctival irritation.

Bacterial resistance among *Staphylococcus aureus* has been reported to occur with the use of topical Fucidin®. As with all antibiotics, extended or recurrent use of fusidic acid may increase the risk of developing antibiotic resistance.

Because of the potential to induce bacterial resistance, and thereby compromise the efficacy of systemically administered Fucidin, the use of Fucidin Topical should be avoided in closed settings e.g. hospitals.

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

Use in pregnancy – Category C

Fusidic acid may cause kernicterus in babies during the first month of life by displacing bilirubin from plasma albumin. Fusidic acid should be avoided when possible during the last month of pregnancy.

ADVERSE EFFECTS

Mild irritation has been reported occasionally. The application of fusidic acid to deep leg ulcers has been associated with pain. Hypersensitivity reactions have been reported rarely.

Based on combined clinical data for Fucidin® cream and Fucidin® ointment, 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.

Hypersensitivity and angioedema have been reported. Adverse effects are listed by MedDRA System Organ Class (SOC) and the individual adverse effects are listed with the most frequently reported first. Within each frequency grouping, adverse effects are presented in the order of decreasing seriousness.

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Reporting Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very common</td>
<td>≥ 1/10</td>
</tr>
<tr>
<td>Common</td>
<td>≥ 1/100 and &lt; 1/10</td>
</tr>
<tr>
<td>Uncommon</td>
<td>≥ 1/1,000 and &lt; 1/100</td>
</tr>
<tr>
<td>Rare</td>
<td>≥ 1/10,000 and &lt; 1/1,000</td>
</tr>
<tr>
<td>Very rare</td>
<td>&lt; 1/10,000</td>
</tr>
</tbody>
</table>
Immune system disorders
*Rare*
Hypersensitivity

Eye disorders
*Rare*
Conjunctivitis

Skin and subcutaneous tissue disorders
*Uncommon*
Dermatitis (including contact dermatitis and eczema)
Rash (including erythematous, pustular, vesicular, macro-papular and papular).
Pruritus
Erythema

*Rare*
Angiodema
Urticaria
Blister

General disorders and administration site conditions
*Uncommon*
Application site pain (including sensation of skin burning)
Application site irritation

**DOSAGE AND ADMINISTRATION**

Usually applied two to three times daily, with or without a covering dressing. When a protective dressing is used, one application daily will generally be sufficient.

The average period of treatment is 7 days. Severe and chronic infections may require longer treatment.

Treatment with Fucidin® ointment will not interfere with other antibacterial therapy.

**OVERDOSAGE**

Overdosage has not been reported.

**PRESENTATION AND STORAGE CONDITIONS**

**PRESENTATION**
Ointment 2%: 5g (physician sample) and 15 g. Not all pack sizes may be available.

Fucidin® ointment is supplied in aluminium tubes with a membrane and a reclosable high density polyethylene screw cap. The aluminium tubes have an inner lacquer of epoxyphenol and a sealant lacquer coating of acrylicacid ester copolymer in the fold area.

**STORAGE CONDITIONS**
Store below 30°C.

In-use shelf life – 60 days
Discard the tube after 60 days of first opening the tube.
NAME AND ADDRESS OF SPONSOR

CSL Limited
(ACN 051 588 348)
45 Poplar Road
PARKVILLE VICTORIA 3052

PHONE (03) 9389 1911

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS

October 1991

DATE OF MOST RECENT AMENDMENT

23 December 2015