

## New Zealand Data Sheet

### 1. PRODUCT NAME

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DP Fusidic Acid Cream

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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Each gram of DP Fusidic Acid Cream contains fusidic acid 20.35 mg, as hydrate, equivalent to fusidic acid 20 mg.

#### **Excipient(s) with known effect**

Butylhydroxyanisole, Cetyl alcohol and Potassium sorbate.  
For the full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

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Smooth and white cream.

### 4. CLINICAL PARTICULARS

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#### **4.1. Therapeutic indications**

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. Dose and method of administration**

##### **Dose**

##### ***Adults and children***

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**

- Infection caused by non-susceptible organisms, in particular, *Pseudomonas aeruginosa*.
- DP Fusidic Acid Cream contraindicated in patients with hypersensitivity to fusidic acid and its salts or to any of the excipients listed in section 6.1

### **4.4. Special warnings and precautions for use**

Bacterial resistance has been reported to occur with the use of fusidic acid applied topically. As with all topical antibiotics, extended or recurrent application may increase the risk of contact sensitisation and the development of antibiotic resistance.

Extended or recurrent use may increase the risk of developing contact sensitisation.

When DP Fusidic Acid Cream is used on the face, care should be taken to avoid the eyes, because fusidic acid can cause irritation of the conjunctiva.

DP Fusidic Acid Cream contains butylhydroxyanisole, cetyl alcohol and potassium sorbate which may cause local skin reactions (e.g. contact dermatitis). Butylhydroxyanisole may also cause irritation to the eyes and mucous membranes.

### **4.5. Interaction with other medicines and other forms of interaction**

No interaction studies have been performed.

### **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 DP Fusidic Acid Cream can be used during pregnancy.

#### **Breast-feeding**

No effects on the breastfed new-born/infant are anticipated since the systemic exposure of the breast-feeding woman is negligible. Topical DP Fusidic Acid Cream can be used during breast-feeding, but it is recommended to avoid applying topical DP Fusidic Acid Cream 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 to topically applied fusidic acid/sodium fusidate is negligible.

### **4.7. Effects on ability to drive and use machines**

DP Fusidic Acid Cream 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 4754 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 according to the following frequency convention:

Very common ( $\geq 1/10$ )

Common ( $\geq 1/100$  to  $<1/10$ )

Uncommon ( $\geq 1/1,000$  to  $<1/100$ )

Rare ( $\geq 1/10,000$  to  $<1/1,000$ )

Very rare ( $<1/10,000$ )

Not known (cannot be estimated from the available data).

System organ class	Frequency	Undesirable effects
Immune system disorders	Rare	Hypersensitivity
Eye disorders	Rare	Conjunctivitis
Skin and subcutaneous tissue disorders	Uncommon	Dermatitis (including contact dermatitis, eczema) Rash* Pruritus, Erythema
	Rare	Angioedema Urticaria Blister
General disorders and administration site conditions	Uncommon	Application site pain (including skin burning sensation), Application site irritation

\*Various types of rash reactions such as erythematous, pustular, vesicular, maculo-papular and papular have been reported. Rash generalised has also occurred.

#### ***Paediatric population***

Frequency, type and severity of adverse reactions in children are expected to be the same as in adults.

#### ***Reporting of suspected adverse reactions***

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected reactions <https://nzphvc.otago.ac.nz/reporting/>

#### **4.9. Overdose**

Overdose is unlikely.

Unless hypersensitivity to fusidic acid or any of the excipients exist, accidental ingestion of DP Fusidic Acid Cream is unlikely to cause any harm. The total quantity of fusidic acid (30 g DP Fusidic Acid Cream contains 600mg 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  $\leq 10$ kg.

Although in this instance a child of this particular age group is unlikely to ingest a whole tube of DP Fusidic Acid Cream. The concentration of the excipients is too low to constitute a safety risk.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

## **5. PHARMACOLOGICAL PROPERTIES**

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### **5.1. Pharmacodynamic properties**

Pharmacotherapeutic group: other antibiotics for topical use, ATC code: D06AX01

#### **Mechanism of action**

Fusidic acid belongs to a unique group of antibiotics, the fusidanes, which act to inhibit bacterial protein synthesis by blocking the lengthening of factor G. This is to prevent it from associating with ribosomes and GTP, thus preventing energy supply to the synthesis process.

As it is the only type of drug available in this family of drugs, there have been no reports of cross resistance to fusidic acid.

#### **Clinical efficacy and safety**

Resistance mechanism(s):

Resistance for fusidic acid can vary geographically and information about local resistance patterns should be obtained through a local microbiology laboratory. In general, resistance occurs in 1-10 % of *Staphylococcus aureus* and 10-20 % of coagulase negative *staphylococci* . Cross-resistance between DP Fusidic Acid Cream and other antibiotics has not been reported.

Sensitivity:

The sensitivity of organisms to fusidic acid is based on the in vitro sensitivity and plasma concentrations that are achieved after systemic therapy. Local treatment causes higher peak concentrations as compared to plasma. However, it is not known how the kinetics of the cream after local application may change the effectiveness of the cream.

Breakpoints:

The following MIC values are recommended to distinguish sensitive and non-sensitive germs: S  $\leq$  1  $\mu$ g/ml and R > 1  $\mu$ g/ml. This breakpoint should be used for the systemic use of fusidic acid. In general, no breakpoints are established for the topical use of antibiotics.

Commonly susceptible species	<i>Staphylococcus aureus</i> and <i>Staphylococcus epidermis</i> (including methycillin resistant and beta lactamase producing strains); <i>Corynebacterium minutissimum</i> ; <i>Clostridium spp.</i> ; <i>Peptococcus spp.</i> ; <i>Peptostreptococcus spp.</i> ; <i>Neiseria spp.</i> ; <i>Bacteroides fragilis</i> .
Inherently resistant organisms	<i>Streptococcus pyogenes</i> ; <i>Streptococcus pneumoniae</i> ; <i>Streptococci viridans</i> ; most gram-negative bacilli including <i>Haemophilus influenza</i> ; <i>Enterobacteriaceae</i> ; <i>Pseudomonas spp.</i> ; <i>Escherichia coli</i> and <i>Klebsiella pneumoniae</i> .

## 5.2. Pharmacokinetic properties

### Absorption

*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

### Elimination

Fusidic acid is excreted mainly in the bile with little excreted in the urine. (Elimination half-lives, total clearance; inter and/or intra-subject variability in total clearance; excretion routes of the unchanged substance and the metabolites including the relative portion of the hepatic and renal eliminated fraction, involvement of transport proteins)

## 5.3. Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the data sheet (refer to section 6). .

## 6. PHARMACEUTICAL PARTICULARS

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### 6.1. List of excipients

DP Fusidic Acid Cream contain butylated hydroxyanisole, cetyl alcohol, glycerol, hydrochloric acid, liquid paraffin, polysorbate 60, potassium sorbate, purified water, white soft paraffin.

### 6.2. Incompatibilities

Not applicable

### **6.3. Shelf life**

Unopened tube: 24 months

Opened tube: 4 weeks

### **6.4. Special precautions for storage**

Store at or below 25°C.

### **6.5. Nature and contents of container**

Aluminium tube with HDPE screw cap

Pack sizes: 15g and 30g

Not all pack sizes may be marketed.

### **6.6. Special precautions for disposal and other handling**

Any unused medicine or waste material should be disposed of in accordance with local requirements.

## **7. MEDICINE SCHEDULE**

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Prescription medicine

## **8. SPONSOR**

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Douglas Pharmaceuticals Ltd

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## **9. DATE OF FIRST APPROVAL**

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06 March 2014

## **10. DATE OF REVISION OF THE TEXT**

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23 January 2019

Summary table of changes

<b>Section Changed</b>	<b>Summary of new information</b>
All	SPC format
4.4,4.6	Additional information based on source datasheet, information on breast feeding and fertility.
4.8	Additional information based on source datasheet
5.1	Updated information based on mechanism of action based on source datasheet. Additional information on clinical efficacy and safety based on source datasheet.