Product Monograph

Including Patient Medication Information

PrFUCIDIN®

Fusidic acid

Cream

For topical use

2% of Fusidic acid

Antibiotic

Sodium fusidate

Ointment

For topical use

2% of Sodium fusidate

Antibiotic

LEO Pharma Inc.

Toronto, Ontario

M5C 1H6

www.leo-pharma.com/canada

Date of Authorization:
2026-05-07

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Recent Major Label Changes

None at time of the most recent authorisation	

Table of Contents

Certain sections or subsections that are not applicable at the time of the preparation of the most recent authorized product monograph are not listed.

Part 1: Healthcare Professional Information

1. Indications

FUCIDIN® Cream (Fusidic acid) and Ointment (Sodium fusidate) is indicated for:

- Use in the treatment of primary and secondary skin infections caused by sensitive strains of *Staphylococcus aureus*, *Streptococcus spp* and *Corynebacterium minutissimum*. Primary skin infections include: impetigo contagiosa and erythrasma. Secondary skin infections include infected wounds and infected burns.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of FUCIDIN Ointment and Cream and other antibacterial drugs, FUCIDIN Ointment and Cream should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.

When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

In addition, local concentrations of FUCIDIN Ointment and Cream are active against other *Corynebacteria spp.* No cross-resistance has been observed to date between FUCIDIN and other antibiotics presently in clinical use.

Resistance to FUCIDIN has readily been induced in vitro. The development of resistance has also been shown to occur in the clinical setting.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

1.1. Pediatrics

No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use (see **7.1.3. Pediatrics**).

2. Contraindications

- FUCIDIN Ointment and Cream are contraindicated in patients who are hypersensitive to these drugs or to any ingredient in the formulations, including any non-medicinal ingredients, or components of the container. For a complete listing, see **6 Dosage Forms, Strengths, Composition and Packaging**.

4. Dosage and Administration

4.1. Dosing Considerations

- FUCIDIN is for topical use only.
- Limiting therapy with FUCIDIN to no more than 14 days at a time will minimize the risk of developing resistance (see **7 Warnings and Precautions, Sensitivity/Resistance**).

4.2. Recommended Dose and Dosage Adjustment

- A small amount of FUCIDIN Ointment or Cream should be applied to the lesion two to three times daily for 7-14 days.
- Whenever the lesion is to be covered with a gauze dressing, less frequent applications (1 or 2 daily) may be used.
- Health Canada has not authorized an indication for pediatric use (see **1.1. Pediatrics, 7.1.3. Pediatrics**).

4.4. Administration

In impetigo contagiosa, it has been shown to be unneccessary to remove the crusts before application of FUCIDIN Ointment or Cream.

When required, incision and drainage of infected skin lesions should be carried out before treatment with FUCIDIN Ointment or Cream.

Due to the excipients, avoid getting FUCIDIN in the eyes (see **7 Warnings and Precautions, Skin**).

4.5. Missed Dose

In the event of a missed dose, the patient should be instructed to apply FUCIDIN as soon as they remember, then continue with the next scheduled application as usual.

5. Overdose

For topically applied fusidic acid, no information concerning potential symptoms and signs due to overdose administration is available.

Systemic consequences of an overdose of the active substance after accidental oral intake are unlikely to occur. The amount of fusidic acid in one tube of FUCIDIN Ointment or Cream does not exceed the oral daily dose of systemic treatment.

For the most recent information in the management of a suspected drug overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669).

6. Dosage Forms, Strengths, Composition, and Packaging

Table 1 – Dosage Forms, Strengths, and Composition

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Topical	Cream, 2% Fusidic acid	all-rac-α-tocopherol, butylhydroxyanisole (E320), cetyl alcohol, glycerol (85%), hydrochloric acid, liquid paraffin, polysorbate 60, potassium sorbate, purified water and white soft paraffin.
Topical	Ointment, 2% Sodium fusidate	all-rac-α-tocopherol, butylhydroxytoluene (E321), cetyl alcohol, liquid paraffin white soft paraffin and wool fat (lanolin).

Description

FUCIDIN Cream is a white to off-white cream. Available in aluminium tubes of 15 g and 30 g covered with internal epoxyphenol lacquer. The tube has re-closable high density polyethylene screw cap.

FUCIDIN Ointment is a translucent yellowish to white ointment. Available in aluminium tubes of 15 g and 30 g covered with internal epoxyphenol lacquer. The tube has re-closable high density polyethylene screw cap.

7. Warnings and Precautions

General

Treatment of severe or refractory skin lesions should be supplemented with the administration of a systemic antibacterial agent.

Reproductive Health

- **Fertility**
  There are no clinical studies with topical FUCIDIN regarding fertility. No effects in women of childbearing potential are anticipated, since systemic exposure following topically applied fusidic acid/sodium fusidate is negligible.

Sensitivity/Resistance

Development of Drug-Resistant Bacteria

Prescribing FUCIDIN Ointment or Cream in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and risks the development of drug-resistant bacteria.

Potential for Microbial Overgrowth

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 FUCIDIN may increase the risk of developing antibiotic resistance. Limiting therapy with topical FUCIDIN to no more than 14 days at a

time will minimize the risk of developing resistance.

Overgrowth of Non-susceptible Organisms

Use of topical antibiotics occasionally allows overgrowth of non-susceptible organisms. If this occurs, or irritation or sensitization develops, treatment with FUCIDIN Ointment or Cream should be discontinued and appropriate therapy instituted.

Skin

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

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

7.1. Special Populations

7.1.1. Pregnancy

The safety of FUCIDIN in the treatment of infections during pregnancy has not been established. There is evidence to suggest that following systemic administration the drug can penetrate the placental barrier. If the administration of FUCIDIN to pregnant patients is necessary, its use requires that the potential benefits be weighed against the possible hazards to the foetus.

Animal studies have not demonstrated teratogenicity with fusidic acid (see **16 Non-Clinical Toxicology**).

7.1.2. Breastfeeding

The safety of FUCIDIN for the treatment of infections in women who are breastfeeding has not been established.

Following systemic administration Fusidic acid has been detected in the milk of nursing mothers.

The use of FUCIDIN during lactation requires that the potential benefits be weighed against the risks to the nursing infant.

It is recommended to avoid applying FUCIDIN on the breast to protect the nursing infant from unintentional oral drug uptake.

7.1.3. Pediatrics

No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

8. Adverse Reactions
8.1. Adverse Reaction Overview

In patients with dermatoses treated with FUCIDIN Ointment, mild irritation that did not usually require discontinuance of therapy has been occasionally reported. The application of FUCIDIN Ointment to deep leg ulcers has been associated with pain. Reports of hypersensitivity reactions have been rare.

8.5. Post-Market Adverse Reactions

The following post-market adverse drug reactions have been reported from worldwide experience with FUCIDIN Cream and FUCIDIN Ointment:

Conjunctivitis, Dermatitis (incl. dermatitis contact, eczema), Rash*, Pruritus, Urticaria, Blister, Erythema, Angioedema, Hypersensitivity, Application site pain and 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.

9. Drug Interactions
9.2. Drug Interactions Overview

No interaction studies have been performed.

9.3. Drug-Behaviour Interactions

The interaction of FUCIDIN with individual behavioral risks (e.g. cigarette smoking, cannabis use, and/or alcohol consumption) has not been studied.

9.4 Drug-Drug Interactions

No interaction studies have been performed. Interactions with systemically administered medicinal products are considered unlikely as the systemic absorption of topical FUCIDIN is negligible.

9.5. Drug-Food Interactions

Interactions with food have not been established.

9.6. Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7. Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10. Clinical Pharmacology
10.1 Mechanism of Action

The antibacterial action of fusidic acid results from the inhibition of bacterial protein synthesis. The drug interferes with amino acid transfer from aminoacylsRNA to protein on the ribosomes. Fusidic acid may be bacteriostatic or bactericidal depending on inoculum size. Although bacterial cells stop dividing almost within two minutes after contact with the antibiotic *in vitro*, DNA and RNA synthesis continue for 45 minutes and 1-2 hours, respectively.

FUCIDIN (fusidic acid) is virtually inactive against Gram-negative bacteria. The differences in activity against Gram-negative and Gram-positive organisms are believed to be due to a difference in cell wall permeability.

Mammalian cells are much less susceptible to inhibition of protein synthesis by FUCIDIN than sensitive bacterial cells. These differences are believed to be due primarily to a difference in cell wall permeability.

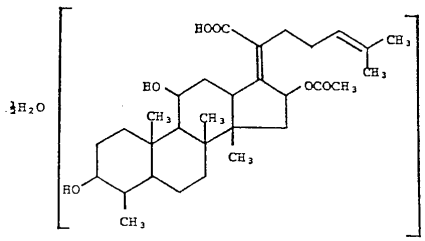
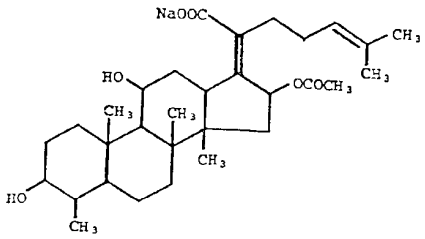
11. Storage, Stability, and Disposal

FUCIDIN Cream:	Store below 30°C.
FUCIDIN Ointment:	Store below 30°C. Use within 3 months of first opening the tube.

Part 2: Scientific Information

13. Pharmaceutical Information

Drug Substance

Non-proprietary name of the drug substance(s):	Fusidic Acid Hemihydrate	Sodium Fusidate
Chemical name:	*ent*-(17Z)-16α-(Acetyloxy)-3β,11β-dihydroxy-4β,8,14-trimethyl-18-nor-5β,10α-cholesta-17(20),24-dien-21-oic acid hemihydrate	Sodium (Z)-ent-16α-(acetyloxy)-3β,11β-dihydroxy-4β,8,14-trimethyl-18-nor-5β,10α-cholesta-17(20),24-dien-21-oate
Molecular formula and molecular mass:	$C_{31}H_{48}O_6 \cdot 1/2H_2O$ 525.7	$C_{31}H_{47}NaO_6$ 538.7
Structural formula:		
Physicochemical properties:	White crystalline powder, insoluble in water.	Sodium fusidate is a white crystalline powder, soluble in one part of water at 20°C.

14. Clinical Trials

The clinical trial data on which the original indication was authorized is not available.

15. Microbiology

In Vitro Studies

FUCIDIN is active in vitro against Gram-positive bacteria and Neisseria species but has almost no antibacterial activity against Gram-negative organisms. The in vitro susceptibility against a range of clinical isolates is illustrated in Table 2.

In vitro sensitivity to FUCIDIN can be determined by the Kirby-Bauer disc diffusion methods using discs containing 10 ug sodium fusidate.

N.B.: It is important to note that this sensitivity test is invalid if blood is present on the agar medium employed as FUCIDIN becomes bound to protein, even in the presence of a very small amount of blood.

The following criteria have been recommended for interpreting the results for *Staphylococcus aureus*:

Sensitive Organisms

Zone equal to or greater than 20 mm diameter (equivalent to an M.I.C. of 2 ug/mL or less).

Resistant Organisms

Zone equal to or less than 19 mm diameter. Streptococcal isolates showing inhibition zones of 12-18 mm diameter may be considered as sensitive to FUCIDIN Ointment or Cream.

Table 2. Spectrum of In Vitro Activity of Sodium Fusidate

Species	No. of strains tested	Cumulative percentage of strains inhibited by given concentration of Fucidin (in ug/mL)**										Activity Range in ug/mL
		0.015	0.03	0.06	0.12	0.25	0.5	1	2*	4	8	
Staph. aureus (penicillin sens.)	149	-	11	50	74	98	100	100	100	100	100	0.03 - 0.3
Staph. aureus (penicillin resist.)												
Strep. pyogenes	10	-	-	-	-	-	-	-	-	40	100	4 - 16
Strep. pneumoniae	13	-	-	-	-	-	-	-	8	46	100	2 - 16
Strep. faecalis	8	-	-	-	-	-	-	13	13	100	100	1 - 8
N. gonorrhoeae	102	-	9	19	30	47	76	92	96	99	100	0.03 - 4
N. meningitidis	108	18	51	81	92	98	100	100	100	100	100	0.015 - 0.5
Clostridium spp.	42	-	-	21	50	74	88	100	100	100	100	0.06 - 1.0
Peptostrep. spp.	15	-	-	13	40	67	73	93	100	100	100	0.06 - 2
Bacteroides fragilis	83	-	-	-	-	1	4	31	80	89	94	0.25 - 16
Bacteroides spp.	72	-	-	7	14	29	47	60	79	90	94	0.06 - 16
Corynebacterium spp.	118	-	-	77	79	-	-	87	-	98	-	0.06 - 12.5

* isolates with MIC's greater than 2 ug/mL are considered to be insensitive at those serum concentrations achievable with normal doses of Fucidin.

** Expressed as sodium fusidate

The possibility of synergism between sodium fusidate and other antibiotics has been tested in meat infusion broth inoculated with sensitive strains of *Staphylococcus aureus*. Synergism has been demonstrated with penicillin V, penicillin G, erythromycin and picromycin.

In another experiment, the M.I.C.'s of combinations of benzyl penicillin or methicillin with fusidic acid were determined by the serial-dilution tube titration method. When the penicillin was added 2 hours before fusidic acid, the combination was synergistic. However when penicillin was added at the same time or later than fusidic acid, the two agents acted antagonistically. It has been suggested that these apparently opposing effects occur because fusidic acid rapidly inhibits protein synthesis, but the action of penicillin requires active cell growth. FUCIDIN and methicillin act antagonistically against staphylococcal strains which are susceptible to methicillin but not in methicillin-resistant strains.

Synergism between the penicillins and fusidic acid has only been observed with strains of *Staphylococcus aureus* that produce small amounts of penicillinase and not with penicillinase-stable penicillins.

In Vivo Studies

Mice Protection: Sodium fusidate, administered orally at levels of 20 to 2500 mcg per dose was tested in vivo in mice infected with a penicillin-resistant strain of *Staphylococcus aureus*, *Streptococcus pyogenes C 203* or *Mycobacterium tuberculosis, var. bovin*, strain Ravenel. Sodium fusidate was active against *Staphylococcus aureus* at all levels, but active against *Streptococcus pyogenes C 203* only at levels of 313 mg/dose and above. The drug did not prolong survival times of mice infected with *Mycobacterium tuberculosis*.

In another study, groups of mice were infected intraperitoneally with *Streptococcus pyogenes C 203*, *Staphylococcus aureus* (penicillin-resistant and penicillin-sensitive) or *Diplococcus pneumoniae SV.1.* When 1 dose of 250 mg/kg sodium fusidate was administered orally 24 or 6 hours prior to the staphylococcal infection, it protected 60% and 80% of the mice treated, respectively. When the single dose of sodium fusidate was administered 4, 2 and 1 hour pre-infection or at the time of infection, 100% of the mice were protected. Sodium fusidate administered subcutaneously failed to protect the mice against *Streptococcus pyogenes C 203* and *Diplococcus pneumonia* infections, regardless of the time of administration. Single subcutaneous and oral doses of sodium fusidate, vernamycin B and erythromycin (4.0, 20.0 and 100 mg/kg) were tested in corticosterone-treated mice which had been infected intradermally with 2 strains of *Staphylococcus aureus*, all three drugs protected the animals from lesions with the 20 mg/kg s.c. dose when given one hour after infection. When administered subcutaneously one hour pre-infection, erythromycin was 5 times more active.

With the oral route, all three drugs provided complete protection with 100 mg/kg given at the time of infection, but 500 mg/kg or more was required when the drugs were administered 3 to 6 hours post-infection. When the same three drugs were tested against an intraperitoneally-induced staphylococcal infection, erythromycin was the most active drug.

Rabbit Protection: Rabbits were inoculated intradermally for 3 days with two different strains of Staphylococcus. When infection was induced 24 hours before the administration of sodium fusidate (32.5, 125 or 500 mg/kg), no beneficial effects on the induced lesions were observed; however, when the staphylococcal lesions were produced at the same time or 24 hours following drug administration, erythema was limited and the size of the lesions remained constant throughout the test period (1 week) for all dose levels.

Resistance in vivo

Although resistance to FUCIDIN has been rapidly induced in vitro, resistant strains have only occasionally been observed in the clinical setting. In one study, only 3 out of 1025 naturally occurring strains of *Staphylococcus aureus* were found to be resistant to FUCIDIN. In another study, only 10 out of 2700 clinical isolates of *Staphylococcus* showed resistance to FUCIDIN and all 10 strains were coagulase-positive Staphylococci. The degree of resistance exhibited by these strains was comparable to the resistance shown by various mutants in vitro.

Resistant strains of *Staph. aureus* have emerged following systemic treatment with FUCIDIN. In one study resistant strains of *Staph. aureus* emerged in 6 of 13 burn patients treated with 500 mg FUCIDIN two or three times daily for 7 days.

16. Non-Clinical Toxicology

General toxicology

Single-dose Toxicity

Mice and Rats: The signs and symptoms of toxicity of fusidic acid and its salts in mice were decreased activity, ataxia and convulsions; in rats, the only symptoms preceding death were decreased activity and slight salivation.

Dogs: Sodium fusidate was administered as a 10% solution by stomach tube to 2 fasted dogs in single doses of 250 and 500 mg/kg, respectively. Two other fasted dogs received the drug in the form of gelatin capsules in doses of 500 and 1500 mg/kg, respectively.

No effects were noted in the dogs receiving 500 mg/kg by capsules. The remaining 3 dogs vomited within 8 to 60 minutes; the dog given 1500 mg/kg was lethargic for 12 hours, but no other effects were observed during a 7 day observation period. A dose-dependent increase in BSP retention times was observed.

Repeat-dose Toxicity

Rats: Sodium fusidate was administered in the diet of 2 groups composed of 5 male and 5 female rats at doses of 0 or 270 mg/kg/day for 4 weeks. A similar group received 500 mg/kg/day for 1 week and subsequently 1200 mg/kg/day for 3 weeks. None of the animals died during testing and no significant lesions attributable to the drug were found. Except for a slight to moderate weight retardation in males in the high dose group, the average rates of growth of the treated animals were comparable to those of the controls.

Dogs: Sodium fusidate was administered in the diet of 3 groups of 2 dogs each. One group served as the control; another group was dosed at 110 mg/kg/day for 4 weeks and the third group at 250 mg/kg for 1 week followed by 470 mg/kg/day for the next 3 weeks. None of the dogs showed any significant gross or micropathological alterations which were considered to be drug-related.

During the second and third weeks, one of the 2 dogs on the low dose showed reduction in appetite which was apparently due to poor palatability of the drug. One of the 2 dogs showed a slight weight loss. In the high dose group reductions in appetite limited drug intake to an average of 470 mg/kg/day. Both these animals had small weight losses, probably associated with reduced food intake.

Rats: Sodium fusidate was administered in the diet to 4 groups of 40 rats at doses of 0, 200, 420 or 840 mg/kg daily for 34 weeks. High dose females and to a lesser degree, high dose males showed a small

retardation of weight gain. Slight neutrophilia was also noted in both high dose males and females. Ten of the 14 high dose males showed mild fatty metamorphosis of the liver without significant cytopathological change.

In another study, rats received sodium fusidate administration orally at a dose of 200 mg/kg/day for 24 weeks. No influence on growth or hematology and no other toxic effects were observed.

In a third study, fusidic acid was administered orally to a group of 25 male and 25 female rats at a dose of 400 mg/kg/day, 6 days a week for 5 months. No hematological changes or other toxic effects were noted.

Guinea Pigs: No toxic effects were seen when sodium fusidate was administered orally to guinea pigs at doses of 80 mg/kg/day for 50 days.

Dogs: Sodium fusidate was included in the diet of 4 groups of 5 dogs in amounts to result in doses of 0, 90, 190 or 300 mg/kg for 26 weeks. Significant changes observed were: weight loss with significantly reduced appetite in one animal on the high dose; however, all other test animals maintained or gained weight comparable to the control group in spite of slightly reduced food intake ascribed by the investigator to poor palatability; one dog on the high dose showed definite increases in plasma bilirubin and BSP; one dog on the intermediate dose showed slight to moderate increases in BSP, SGPT and alkaline phosphatase; one dog on the low dose showed a moderate increase in alkaline phosphatase and a slight increase in plasma bilirubin.

In another study, post-mortem examination revealed mild to moderate liver cell damage in one high dose dog (400 mg/kg/day) at 26 weeks, but the other animals showed no morphological changes with this dose attributable to the drug.

Genotoxicity

No studies have been performed to evaluate the genotoxic potential of fusidic acid and sodium fusidate.

Carcinogenicity

No long-term animal studies have been performed to evaluate the carcinogenic potential of fusidic acid and sodium fusidate.

Reproductive and developmental toxicology

Two groups, each comprised of 20 male and 20 female rats, received either 0 or 400 mg/kg sodium fusidate per day for 2 weeks before mating to weaning. Caesarian sections were performed on half the dams on the 20th day; the remainder were allowed to deliver naturally.

There were no significant differences between the treated and control dams with respect to per cent resorptions, the condition of the uteri or the number and weights of the pups. No soft tissue abnormalities were found in the pups of either group but skeletal anomalies (control group 2 pups missing ribs and dosed group 1 pup occipital bone formation incomplete and 1 pub rib deformities) appeared in 4% of the pups in both groups. The viability and lactation indices, reflecting neonatal development, were higher in the treated group than the control group, but all values were within normal limits.

Teratology Studies

Mice: Pregnant mice were divided into 3 groups of 16-19 animals each and given daily doses of 20, 100 and 200 mg/kg sodium fusidate by gavage from the 6th to 15th day of gestation. Another group of 23 pregnant mice, serving as controls, received just water by gavage. On the 18th day of pregnancy, half the dams were sacrificed. The remainder was allowed to go to term.

Sex distribution of fetuses and young, fetal weight, birth weight and weight increase were normal and similar for all groups. The mean incidence of resorption was 1.2, 1, 0.5 and 0.6 per dam for the 20, 100 and 200 mg/kg groups and control group, respectively. Average litter size in the treated group did not differ significantly from that of the controls in any of the groups.

Rats: Pregnant rats were divided into 3 groups of 29-31 animals each and given daily doses of 20, 100 or 200 mg/kg sodium fusidate by gavage from the 3rd to the 15th day of gestation. Another group of 59 pregnant rats, serving as controls, received just water by gavage. On the 21st day of pregnancy, half the dams were sacrificed. The remaining dams were allowed to go to term.

The average rate of resorption was 1.2, 1.8, 1.7 and 1.3 per dam for the 20, 100 and 200 mg/kg and control groups, respectively. Litter size and sex distribution of the fetuses and young of the dosed animals were comparable to the controls with no dose-related differences. Birth weights and weight gain over a 4-month period were comparable for all groups. No fetal deformities were observed in any group.

Rabbits: Eighteen pregnant rabbits were treated orally with 125 mg sodium fusidate in tablet form once per day from the 6th to the 18th day of pregnancy. Eleven pregnant animals, serving as controls, received a placebo tablet each day. On the 30th day of pregnancy 9 treated animals and 3 controls were sacrificed. The remaining animals were allowed to go to term.

Sex distribution of fetuses and young, fetal and birth weighs and weight gain were normal and similar for both groups. Three dead foetuses were found in each of 2 treated animals and in 1 control animal. Average litter size was lower in the treated group (4.8 young per litter) than in the control group (7.6 young per litter). Macroscopic examinations of the young failed to reveal any teratogenic or other abnormalities.

Special toxicology

Skin Tolerance Studies

Daily application of FUCIDIN Ointment (sodium fusidate) to the ears of rabbits for a period of one month evolved neither general intolerance, local irritation to the eye, change in capillary permeability of the treated region, nor sensitization to the irritant effects of locally applied chloroform.

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

FUCIDIN®

Fusidic acid, 2% Cream

Sodium Fusidate, 2% Ointment

This Patient Medication Information is written for the person who will be taking **FUCIDIN®**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **FUCIDIN®**, talk to a healthcare professional.

What FUCIDIN® is used for:

FUCIDIN® is used to treat conditions where the skin is infected by germs (bacteria), such as:

- Impetigo (a weeping, crusty and swollen patch of skin)
- Erythrasma (brown, scaly patches of skin, usually in skin fold areas, such as armpits or under breasts)
- Infected cuts and burns

Antibacterial drugs like FUCIDIN® Cream and Ointment treat only bacterial infections. They do not treat viral infections.

How FUCIDIN® works:

FUCIDIN® Cream contains fusidic acid. FUCIDIN® Ointment contains sodium fusidate. Both medicines are antibiotics which are used to kill bacteria that cause infections.

The ingredients in FUCIDIN® are:

Medicinal ingredients: FUCIDIN® Cream – 2% fusidic acid (hemihydrate)

FUCIDIN® Ointment – 2% sodium fusidate

Non-medicinal ingredients: FUCIDIN® Cream – all-rac-α-tocopherol, butylhydroxyanisole (E320), cetyl alcohol, glycerol (85%), hydrochloric acid, white soft paraffin, liquid paraffin, polysorbate 60, potassium sorbate, purified water.

FUCIDIN® Ointment – all-rac-α-tocopherol, butylhydroxytoluene (E321), cetyl alcohol, white soft paraffin, liquid paraffin, wool fat (lanolin).

FUCIDIN® comes in the following dosage forms:

FUCIDIN® Cream is a white to off-white cream.

FUCIDIN® Ointment is a translucent yellowish to white Ointment.

Do not use FUCIDIN® if:

- you are allergic to any ingredient in FUCIDIN® Cream or Ointment or to any component of the container.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take FUCIDIN®. Talk about any health conditions or problems you may have, including if you:

- are pregnant or if you become pregnant during treatment with FUCIDIN®
- are breastfeeding or intend to breastfeed

Other warnings you should know about:

- Do not use Fucidin® Cream or Ointment more than 14 days.
- If you use Fucidin® Cream or Ointment more than 14 days the bacteria may become resistant to antibiotics.

Skin irritation:

- Fucidin® Cream contains butylhydroxyanisole, cetyl alcohol and potassium sorbate as non-medicinal ingredients.
- Fucidin® Ointment contains cetyl alcohol, hydrous lanolin and butylhydroxytoluene (E321) as non-medicinal ingredients.
- These ingredients may cause a red, itchy rash (contact dermatitis) on your skin where Fucidin® Ointment is applied. Butylhydroxytoluene (E321) may also cause irritation to the eyes and mucous membranes (such as lips or genital area).
- Do not let FUCIDIN® get into your eyes. If the cream or the Ointment gets into the eye, this may lead to eye irritation.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines

How to take FUCIDIN®:

- Although you may feel better early in your treatment, FUCIDIN® Cream and Ointment should be used exactly as directed.
- Misuse or overuse of FUCIDIN® Cream and Ointment could lead to the growth of bacteria that will not be killed by FUCIDIN® Cream and Ointment (resistance). This means that FUCIDIN® Cream and Ointment may not work for you in the future.
- Do not share your medicine.

Usual dose:

Without a covering dressing: apply a small amount of FUCIDIN® Cream or Ointment to the affected area two to three times daily for 7-14 days.

With a covering dressing: one or two applications daily may be enough.

It is not necessary to remove any crusts caused by impetigo before applying FUCIDIN®.

Overdose:

If you think you, or a person you are caring for, have taken too much [BRAND NAME], contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

If you forget to use FUCIDIN®, use it as soon as you remember. Next time, follow your regular application routine.

Possible side effects from using FUCIDIN®:

These are not all the possible side effects you may feel when taking FUCIDIN®. If you experience any side effects not listed here, contact your healthcare professional. Please also see **7 Warnings and Precautions**.

Side effects from using FUCIDIN® may include:

- itching, burning sensation, irritation or pain in the area where the medication is used
- various types of skin rashes (dermatitis)
- Skin redness
- Blistering of the skin
- Hives — also known as urticaria (a skin reaction that causes itchy welts)

Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Rare			
Allergic reactions (angioedema): dizziness, itching, severe rash, swelling (mouth, throat, lips, hands), trouble breathing			✓
Conjunctivitis: pink or red colour in the white of the eye(s), watery eyes, itchy or scratchy eyes, discharge from the eye(s), crusts on the eyelids or lashes		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

FUCIDIN Cream: Store below 30°C.

FUCIDIN Ointment: Store below 30°C. Use within 3 months of first opening the tube.

Keep out of reach and sight of children.

If you want more information about FUCIDIN®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (Drug Product Database: Access the database); the manufacturer's website [website]; or by calling 1-800-263 4218

This leaflet was prepared by LEO Pharma Inc.

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