PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

STRAMUCIN™

Mupirocin Cream USP
2% (w/w) mupirocin (as mupirocin calcium)

Topical Antibiotic

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Date of Initial Approval: TBD

Date of Preparation: November 21, 2018

Submission Control No: 209943

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PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

STRAMUCIN™ (Mupirocin Cream USP 2% w/w as mupirocin calcium) is indicated topically for the treatment of secondarily infected traumatic lesions such as small lacerations, sutured wounds or abrasions.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of mupirocin cream and other antibacterial drugs, mupirocin 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.

1.1 Pediatrics

Pediatrics (18 months – 16 years of age): Based on the data submitted and reviewed by Health Canada, the safety and efficacy of mupirocin 2% cream in pediatric patients have been established; therefore, Health Canada has authorized an indication for pediatric use.

1.2 Geriatrics

Geriatrics (> *65 years of age*): No overall difference in the efficacy or safety of mupirocin 2% cream was observed in this patient population when compared with that observed in younger patients.

2 CONTRAINDICATIONS

STRAMUCIN™ is contraindicated in patients with known hypersensitivity to mupirocin or any of the excipients of mupirocin cream (see DOSAGE FORMS, COMPOSITION AND PACKAGING).

3 SERIOUS WARNINGS AND PRECAUTIONS BOX

STRAMUCIN™ is not suitable for ophthalmic or intranasal use. Care should be taken to avoid contact with the eyes.

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

For Topical Use Only

4.2 Recommended Dose and Dosage Adjustment

Apply a small amount of STRAMUCIN™, with a cotton swab or gauze pad, to the affected area 3 times daily for up 10 days.

Discontinue use and consult a physician if condition worsens or if irritation occurs. Scabs do not have to be removed. The treated area may be covered by a dressing. Wash your hands before and after applying.

No dosage adjustment is necessary for:
- Adults/Children/Elderly
- Patients with hepatic or renal impairment.

Do not mix with other preparations as there is a potential risk of dilution, resulting in a reduction in the antibacterial activity and potential loss of stability of the mupirocin in the cream.

4.3 Missed Dose

If an application of STRAMUCIN™ is missed, apply as soon as you remember or when it is convenient.

5 OVERDOSAGE

For management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Table 1 – Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Topical	Cream: 2% w/w mupirocin (as mupirocin calcium) in 15-gram and 30-gram tubes	benzyl alcohol, glycerol monostearate, mineral oil, phenoxyethanol, polyoxyl 20 cetostearyl ether, purified water and xanthan gum.

7 WARNINGS AND PRECAUTIONS

Please see the Serious Warnings and Precautions Box at the beginning of Part I: Health Professional Information.

General

In the rare event of a possible sensitization reaction or severe local irritation occurring with the use of the product, treatment should be discontinued, the product should be wiped off and appropriate alternative therapy for the infection instituted. As with other antibacterial products, prolonged use may result in overgrowth of non-susceptible organisms.

Avoid contact with the eyes.

Prescribing mupirocin 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.

Ear/Nose/Throat

STRAMUCIN™ is not suitable for intranasal use.

Gastrointestinal

Pseudomembranous colitis has been reported with the use of antibiotics and may range in severity from mild to life-threatening. Therefore, it is important to consider its diagnosis in patients who develop diarrhea during or after antibiotic use. Although this is less likely to occur with topically applied mupirocin, if prolonged or significant diarrhea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately and the patient investigated further.

Ophthalmologic

STRAMUCIN™ is not suitable for ophthalmic use. Avoid contact with the eyes. If contaminated, the eyes should be thoroughly irrigated with water until the cream residue has been removed.

Sensitivity/Resistance

The use of this product may result in overgrowth of non-susceptible organisms. Also the use of this product may result in localized site irritation. Please see General Warning section above for further information or PART II MICROBIOLOGY for further information.

Sexual Health

Reproduction

There are no data on the effects of mupirocin on human fertility. Studies in rats showed no effects on fertility (see PART II TOXICOLOGY).

Skin
In the rare event of a possible sensitization reaction or severe local irritation occurring with the use of the product, treatment should be discontinued, the product should be wiped off and appropriate alternative therapy of the infection instituted.

As with other topical antibacterial products, prolonged use may result in overgrowth of non-susceptible organisms.

7.1 Special Populations

7.1.1 Pregnant Women

The safety of STRAMUCIN™ in the treatment of infections during pregnancy has not been established. If administration to pregnant patients is considered necessary, its potential benefits should be weighed against the possible hazards to the fetus.

7.1.2 Breast-feeding

Caution should be exercised when STRAMUCIN™ is administered to nursing mothers. If a cracked nipple is to be treated, lactation from the affected breast should be maintained by manual expression until the end of treatment. During this time, milk from the affected breast should be discarded.

7.1.3 Pediatrics

Pediatrics (18 months to 16 years): The safety and effectiveness of mupirocin cream have been established in the age-groups 18 months to 16 years [see **ADVERSE REACTIONS**].

7.1.4 Geriatrics

In 2 adequate and well-controlled trials, 30 subjects older than 65 years were treated with other formulations of mupirocin cream. No overall difference in the efficacy or safety of mupirocin cream was observed in this patient population when compared with that observed in younger patients.

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

The following local adverse reactions have been reported during therapy with mupirocin cream: itching, burning, erythema, stinging, and dryness. It was usually not necessary to discontinue therapy due to these adverse reactions. Systemic allergic reactions have been reported with mupirocin cream. Cutaneous sensitization reactions to mupirocin or the cream base have been reported rarely.

8.2 Clinical Trial Adverse Reactions

Because clinical trials are conducted under very specific conditions, the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse reaction information from clinical trials is useful for identifying drug-related adverse events and for approximating rates.

In previously conducted clinical studies with other formulations of mupirocin cream, the following adverse reactions were reported in connection with the use of mupirocin cream: headache, rash, and nausea.

Other adverse reactions reported rarely included: abdominal pain, burning at application site, cellulitis, dermatitis, dizziness, pruritus, secondary wound infection, and ulcerative stomatitis.

In a multi-center, double-blind, randomized, parallel-group, vehicle-controlled study in patients 18 months of age or older with secondarily infected traumatic skin lesions the safety and efficacy of STRAMUCIN™ was compared against a vehicle cream. The most frequently occurring treatment emergent adverse events (TEAEs) were nasopharyngitis (2.7% Test, 1.8% Vehicle) and headache (2.7% Test, 1.4% Vehicle) in the Test group, and pyrexia in the Vehicle group (0% Test, 2.7% Vehicle). The only TEAEs that were considered possibly, probably, or definitely related to study medication were application site pruritus and worsening of ingrowing toenail in the Test group and hypersensitivity and wound complication in the Vehicle group, which occurred in only 1 subject each. Two subjects in the Vehicle group discontinued due to an adverse event.

8.3 Clinical Trial Adverse Reactions (Pediatrics)

In a clinical trial with mupirocin cream, the most frequently reported adverse experiences in the pediatric population, irrespective of relationship to drug (158 patients were treated with mupirocin cream while 152 patients received topical placebo) were nasopharyngitis (3.8%) and headache (2.5%) for topical mupirocin cream, and pyrexia (3.9%), nasopharyngitis (2.0%), cough (1.3%) and upper respiratory infection (1.3%) for topical placebo.

8.4 Post-Market Adverse Reactions

Very rare adverse events consisting of systemic allergic reactions, including anaphylaxis, urticaria, angioedema, and generalized rash have been reported in patients treated with formulations of mupirocin.

9 DRUG INTERACTIONS

9.1 Overview

No drug interactions with mupirocin cream have been identified.

10 ACTION AND CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

Mupirocin inhibits bacterial protein synthesis by reversibly and specifically binding to bacterial isoleucyltransfer RNA (tRNA) synthetase.

Mupirocin is bactericidal at concentrations achieved by topical administration. Mupirocin is highly protein bound (greater than 97%) and the effect of wound secretions on the minimum inhibitory concentrations (MICs) of mupirocin has not been determined.

10.2 Pharmacodynamics

Mupirocin is a topical antibacterial agent showing in vivo activity against Staphylococcus aureus (including methicillin-resistant strains), S. epidermidis and beta-hemolytic Streptococcus species.

The *in vitro* spectrum of activity includes the following bacteria:

Commonly Susceptible Species:

- *Staphylococcus aureus*[1,2]
- *Staphylococcus epidermidis*[1,2]
- *Coagulase-negative staphylococci*[1,2]
- *Streptococcus species*[1]
- *Haemophilus influenzae*
- *Neisseria gonorrhoeae*
- *Neisseria meningitidis*
- *Moraxella catarrhalis*
- *Pasteurella multocida*

[1]Clinical efficacy has been demonstrated for susceptible isolates in approved clinical indications.
[2]Including beta-lactamase producing strains and methicillin-resistant strains

Resistant Species:

- *Corynebacterium* species
- *Enterobacteriaceae*
- Gram negative non-fermenting rods
- *Micrococcus* species
- Anaerobes

Mupirocin susceptibility (MIC) breakpoints for Staphylococcus spp.

Susceptible: Less than or equal to 1 microgram/mL
Intermediate: 2 to 256 micrograms/mL
Resistant: greater than 256 micrograms/mL

10.3 Pharmacokinetics

Absorption:
Systemic absorption of mupirocin through intact human skin is minimal. The systemic absorption of mupirocin was studied following application of mupirocin cream 3 times daily for 5 days to various skin lesions greater than 10 cm in length or 100 cm^2 in area in 16 adults (aged 29 to 60 years) and 10 children (aged 3 to 12 years). Some systemic absorption was observed as evidenced by the detection of the metabolite, monic acid, in urine. Data from this trial indicated more frequent occurrence of percutaneous absorption in children (90% of subjects) compared with adults (44% of subjects); however, the observed urinary concentrations in children (0.07 to 1.3 mcg per mL [1 pediatric subject had no detectable level]) are within the observed range (0.08 to 10.03 mcg per mL [9 adults had no detectable level]) in the adult population. In general, the degree of percutaneous absorption following multiple dosing appears to be minimal in adults and children.

The effect of the concurrent application of mupirocin cream with other topical products has not been studied [see **Drug Interactions**].

Distribution:
No data is available.

Metabolism:
Mupirocin is suitable only for topical application. Following intravenous or oral administration, mupirocin is rapidly metabolized. The principal metabolite, monic acid, demonstrates no antibacterial activity.

Elimination:
Mupirocin is rapidly eliminated from the body by metabolism to its inactive metabolite monic acid which is rapidly excreted by the kidney.

Special Populations and Conditions:
No data available.

11 STORAGE, STABILITY AND DISPOSAL

STRAMUCIN™ is supplied in 15-gram and 30-gram tubes.

Store between 15ºC and 25ºC. Do not freeze.

PART II: SCIENTIFIC INFORMATION

12 PHARMACEUTICAL INFORMATION

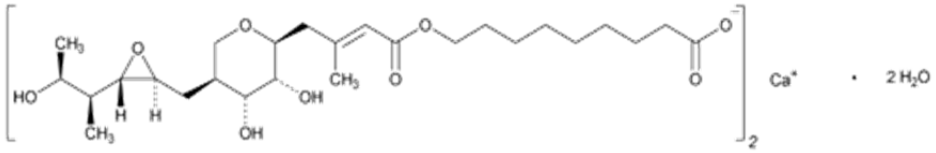
Drug Substance

Proper name: Mupirocin calcium dihydrate
Chemical name: (αE,2S,3R,4R,5S)-5-[(2S,3S,4S,5S)-2,3-epoxy-5-hydroxy-4-methylhexyl]tetrahydro-3,4dihydroxy-β-methyl-2H-pyran-2-crotonic acid, ester with 9-hydroxynonanoic acid, calcium salt (2:1), dihydrate

Molecular formula: $C_{52}H_{86}O_{18}Ca \cdot 2H_2O$

Molecular mass: 1075.3

Structural formula:



Physicochemical properties: Mupirocin calcium is a white to almost white powder.

13 CLINICAL TRIALS

A multi-center, double-blind, randomized, parallel-group, vehicle-controlled study was conducted to compare the safety and efficacy of STRAMUCIN™ against a vehicle cream in the treatment of secondarily infected traumatic skin lesions (e.g., small lacerations, sutured wounds and abrasions).

Table 2- Summary of Patient Demographics for Clinical Trials in Secondarily Infected Traumatic Skin Lesions

Study #	Trial design	Dosage, route of administration and duration	Study subjects (n)	Mean age (y)	Sex M / F
GLK 605	multi-center, double-blind, randomized, vehicle-controlled, parallel-group	• STRAMUCIN™ cream • Vehicle cream Topical, 3 times daily X 10 days for a total of 30 applications	220 219	13.5 ± 13.3 12.4 ± 13.2	56% / 44% 55% / 45%

The baseline culture results and clinical signs and symptoms were similar for both treatment groups. The primary efficacy variable was the clinical response as determined at Visit 4/Follow-up (7 days post-treatment). Clinical response was measured using the 4-point the Skin Infection Rating Scale (SIRS) scores for signs and symptoms of infection (exudate/pus, crusting, erythema/inflammation, tissue warmth, and edema scored by the investigator and pain and itching scored by the subject) and bacterial response was based on bacteriologic cultures.

Table 3- Primary Efficacy Analysis: n(%) of Clinical Success at Visit 4/Follow-up

Analysis Population Statistics	Test	Vehicle	P-value[a]
Per-protocol (PP), N	175	165	
n (%) Clinical Success	158 (90.3%)	117 (70.9%)	< 0.001
Modified intent-to-treat (mITT), N	181	176	
n (%) Clinical Success	164 (90.6%)	124 (70.5%)	< 0.001

[a] P-values for treatment comparison from Cochran-Mantel-Haenszel (CMH) test for general association stratified by site.
[b] Clinical Success was defined as achieving complete resolution (SIRS scores of 0) or sustained improvement (SIRS scores of 0 for exudate/pus, crusting, tissue warmth, edema and pain; and 0 or 1 for erythema/inflammation and itching) of signs and symptoms of infection. No additional antibiotic therapy required after End of Treatment.

Results demonstrated that STRAMUCIN™ is superior to the vehicle in achieving complete resolution or sustained improvement of the signs and symptoms of infection ($p < 0.001$). Bacterial eradication rates of pathogenic organisms at follow-up were also significantly greater after treatment with STRAMUCIN™ than vehicle cream ($p < 0.001$).

Pediatrics

There were 132 pediatric subjects aged 18 months to 16 years enrolled per protocol in the secondarily infected skin lesion trials population treated with mupirocin cream. Subjects were randomized to either 10 days of topical mupirocin cream 3 times daily or 10 days of topical placebo. Clinical efficacy at follow-up (7 days post-treatment) in the per-protocol populations was 91.7% (121 of 132) for mupirocin cream and 69.0% (87 of 126) for topical placebo ($p< 0.001$).

14 MICROBIOLOGY

Mupirocin is active against those micro-organisms responsible for the majority of skin infections. It is particularly active against staphylococci, including methicillin-resistant strains. It is also active against many Gram-negative bacteria as a result of the high concentrations achieved after topical administration. Most strains of *Morganella morganii, Serratia marcescens* and *Pseudomonas aeruginosa* are resistant. It is not active against most anaerobic bacteria, mycobacteria, mycoplasma, chlamydia, yeast, and fungi. The in vitro activity of mupirocin against strains of various organisms is presented in the table below.

Table 4- In Vitro Activity of Mupirocin

Laboratory Species	MIC (µg/mL)
Aerobic Gram-Positive	
Straphylococcus	
S. epidermidis	0.5
S. haemolyticus	0.5
S. hominis	0.5
S. saprophyticus	0.12
S. aureus	0.25
Streptococcus	
S. pyogenes	0.12
S. species GROUP G	0.12
S. species GROUP C	0.25
S. agalactiae	0.5
S. mutans	0.5
S. sanguis	1.0
S. faecium	32
S. faecalis	64
Corynebacterium	
C. hofmannii	64
C. xerosis	>128
C. group	>128
Bacillus subtillis	0.12
Micrococcus luteus	>128

Aerobic Gram-Negative	
Neisseria	
N. meningitidis	0.02
N. gonorrhoeae	0.05
Haemophilus influenzae	0.12
Pasteurella multocida	0.25
Branhamella catarrhalis	0.2
Proteus	
P. vulgaris	64
P. mirabilis	128
Enterobacter	
E. cloacae	64
E. aerogenes	128
Escherichia coli	128
Klebsiella pneumoniae	128
Citrobacter freundii	128
Serratia marcescens	1600
Pseudomonas aeruginosa	6400
Morganella morganii	6400
Anaerobic Bacteria	
Peptostreptococcus anaerobius	32
Clostridium	
C. sporogenes	32
C. difficile	32
Propionibacterium	
P. acnes	>128
P. granulosum	>128
P. avidum	>128
Peptococcus	
P. prevotii	>128
P. asaccharolyticus	>128
Bacteriodes fragilis	>128

Effect of Inoculum Size:
There is only a slight effect of inoculum size on mupirocin calcium cream's minimum inhibitory concentrations (MIC's). For Staphylococcus aureus, inocula ranging from 10^6 cells/mL (undiluted) to 10 cells/mL (10^5 dilution) resulted in a two- to four-fold variation in the MIC values.

Effect of Composition and pH of Medium:
The antibacterial activity of mupirocin was not influenced by the composition of the medium. The MIC values of mupirocin were generally two-to four-fold lower at acid pH (6.0) and two- to four-fold higher at alkaline pH (8.0) than those observed in the medium of normal pH (7.4).

Effect of Serum:
Mupirocin was highly bound to serum protein (96.5% bound) and consequently, the activity of the compound was markedly reduced in the presence of human serum.

Minimum Bactericidal Concentrations:
The MIC values of mupirocin against strains of Staphylococcus aureus ranged from 0.12 µg/mL to 2.0 µg/mL and the MBC values from 0.5 - >128 µg/mL. In most cases, the MBC values were from eight- to thirty-two-fold higher than the corresponding MIC values.

Development of Resistance:
The selection of mupirocin-resistant variants of Staphylococcus aureus after repeated exposure to increasing concentrations of the compound, occurred in a slow and stepwise fashion.

Cross-resistance to Other Antibiotics:
There is no evidence of cross-resistance between mupirocin and other antimicrobial drugs.

15 NON-CLINICAL TOXICOLOGY

Long-term studies in animals to evaluate carcinogenic potential of mupirocin calcium have not been conducted.

Results of the following studies performed with mupirocin calcium or mupirocin sodium in vitro and in vivo did not indicate a potential for genotoxicity: rat primary hepatocyte unscheduled DNA synthesis, sediment analysis for DNA strand breaks, Salmonella reversion test (Ames), Escherichia coli mutation assay, metaphase analysis of human lymphocytes, mouse lymphoma assay, and bone marrow micronuclei assay in mice.

Mupirocin administered subcutaneously to rats in this pre- and post-natal development study (dosed during late gestation through lactation) was associated with reduced offspring viability in the early postnatal period at a dose of 106.7 mg per kg, in the presence of injection site irritation and/or subcutaneous hemorrhaging. This dose is 14 times the human topical dose (approximately 60 mg mupirocin per day) based on calculations of dose divided by the entire body surface area and did not result in impaired fertility or impaired reproductive performance attributable to mupirocin. The no-observed adverse effect level in this study was 44.2 mg per kg per day, which is 6 times the human topical dose.

Developmental toxicity studies have been performed with mupirocin administered subcutaneously to rats and rabbits at doses up to 160 mg per kg per day during organogenesis. This dose is 22 and 43 times, respectively, the human topical dose (approximately 60 mg mupirocin per day) based on calculations of dose divided by the entire body surface area. Maternal toxicity was observed (body weight loss/decreased body weight gain and reduced feeding) in both species with no evidence of developmental toxicity in rats.

In rabbits, excessive maternal toxicity at the high dose precluded the evaluation of fetal outcomes. There was no developmental toxicity in rabbits at 40 mg per kg per day, 11 times the human topical dose based on calculations of dose divided by the entire body surface area.

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

STRAMUCIN™
Mupirocin Cream USP
2% (w/w) mupirocin (as mupirocin calcium)

Read this carefully before you start taking **STRAMUCIN™**. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **STRAMUCIN™**.

Serious Warnings and Precautions

STRAMUCIN™ should not be used in or around your eyes or nose. Care should be taken to avoid contact with the eyes.

What is STRAMUCIN™ used for?

STRAMUCIN™ is used for the topical treatment of minor bacterial skin infections and minor infection in small cuts, wounds or abrasions.

How does STRAMUCIN™ work?

STRAMUCIN™ is an antibiotic. It heals minor cuts, wounds and abrasions in the skin by killing or controlling the growth of the bacteria.

What are the ingredients in STRAMUCIN™?

Medicinal ingredient: mupirocin (as mupirocin calcium)

Non-medicinal ingredients: benzyl alcohol, glycerol monostearate, mineral oil, phenoxyethanol, polyoxyl 20 cetostearyl ether, purified water and xanthan gum.

STRAMUCIN™ comes in the following dosage form:

A topical cream containing 2% (w/w) mupirocin (as mupirocin calcium).

Do not use STRAMUCIN™:

- If allergic to mupirocin or any of the ingredients in the mupirocin cream. Signs of an allergic reaction may include local irritation, itchy skin rash, shortness of breath, and swelling of the face or tongue.
- In or around your eyes, nose or mouth.
- On large area of the body or damaged skin.
- Around surgically inserted tube or at the site of intravenous injection.

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

- Allergic to mupirocin or any other ingredients in the product.
- Pregnant or plan to become pregnant.
- Breastfeeding your baby. If you are applying STRAMUCIN™ to the nipple area, wash thoroughly before breastfeeding or manual expression of milk. If a cracked nipple is to be treated, lactation from the affected breast should be maintained by manual expression until the end of treatment. During this time, milk from the affected breast should be discarded."
- Taking any other medicines, if you have taken any recently, or, if you start taking new ones. This includes any new types of medicines you bought without prescription and natural health products
- Have kidney or liver problems

This medicine is for external use only.

Other warnings you should know about:

- Care should be taken to avoid contact with the eyes. If this medicine does get into your eyes, wash them out immediately, with large amounts of cool tap water.

- Discontinue use and consult with your doctor if condition worsens, if irritation or diarrhea or stomach cramp occurs, or if there is no improvement after 10 days.

- Antibacterial drugs like STRAMUCIN™ treat **only** bacterial infections. They do not treat viral infections such as the common cold. Although you may feel better early in treatment, STRAMUCIN™ should be used exactly as directed. Misuse or overuse of STRAMUCIN ™ could lead to the growth of bacteria that will not be killed by STRAMUCIN™ (resistance). This means that STRAMUCIN™ may not work for you in the future. Do not share your medicine.

- Long term use may result in development of antibiotic resistance.

The following may interact with STRAMUCIN™:

No drug interactions with mupirocin cream have been identified.

How to take STRAMUCIN™:

Usual dose:

Adults and children 18 months and older:

Wash your hands before and after applying STRAMUCIN™.

Apply a small amount of STRAMUCIN™, with a cotton swab or gauze pad, to the affected area 3 times daily for up 10 days.

It is important that you take the full course of STRAMUCIN™ until the infection has fully cleared up or for up to 10 days. Don't stop early as your symptoms may disappear before the infection is fully cleared.

Scabs do not have to be removed. The treated area may be covered by a gauze dressing.

Do not mix STRAMUCIN™ with other lotions, creams or ointments. This may dilute STRAMUCIN™, which may affect your treatment.

Overdose:

If you think you have taken too much STRAMUCIN™, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If an application of STRAMUCIN™ is missed, apply as soon as you remember or when it is convenient, then continue as before.

What are possible side effects from using STRAMUCIN™?

These are not all the possible side effects you may feel when taking STRAMUCIN™. If you experience any side effects not listed here, contact your healthcare professional.

Side-effects with STRAMUCIN™ are generally mild. A few people may experience some unwanted effects. Allergic responses (such as rash, local pain or swelling) have been reported rarely.

If you get a skin reaction, stop using STRAMUCIN™. Wipe off any cream and tell your doctor as soon as possible.

Serious side effects and what to do about them				
Symptom / effect		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
COMMON	Application Site Allergic Reaction (skin: burning sensation, itchy, redness of the skin and swelling)		✓	✓
Very RARE	Systemic Allergic Reaction: raised itchy rash, swelling of the face or mouth, difficulty in breathing		✓	✓
UNKNOWN	Inflammation of the colon (Large Bowel); symptoms: diarrhea, usually with blood and mucus, stomach pain, fever		✓	✓

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 (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

Storage:

Store between 15ºC and 25ºC. Do not freeze.
Keep out of reach and sight of children.

If you want more information about STRAMUCIN™:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada.html); or by calling Glenmark Pharmaceuticals Canada Inc. at 1-844-801-7468.

This leaflet was prepared by Glenmark Pharmaceuticals Canada Inc.

Last Revised: Nov-21-2018