SAME SIZE ARTWORK
LEAFLET SIZE : 150 mm x 320 mm

25 mm

20 mm

Scheduling status: S2

Proprietary Name and Dosage Form:

SUPIROBAN OINTMENT

glenmark

The Composition of the Medicine

The active ingredient (medicine) contained in
Supiroban Ointment is mupirocin. 1 g of the ointment contains 20 mg of mupirocin.

Supiroban Ointment also contains the following inactive raw materials:

- Polyethylene Glycol 350
- Polyethylene Glycol 400

Indications and Use
What is Supiroban Ointment used for?

Supiroban Ointment is indicated for the topical treatment of primary and secondary skin infections.

Supiroban Ointment may be used to avoid bacterial contamination of small wounds, incisions and other clean lesions and to prevent infection of abrasions and small cuts and wounds.

Instructions before applying Supiroban ointment

(i) Contraindications (Who should not use Supiroban ointment)

Do not use Supiroban ointment if you are allergic to mupirocin (the active ingredient in Supiroban Ointment), or to the inactive ingredients. Please refer above for a list of inactive ingredients.

Do not use Supiroban Ointment to treat skin lesions infected with a type of bacteria called *Pseudomonas aeruginosa.*

(ii) Precautions and (iii) Warnings

Tell your doctor about any prescription and non-prescription medicines you are using, including natural or herbal remedies. Tell your doctor if you:

- Ever had kidney problems
- Are pregnant or plan to become pregnant or are breast feeding your baby while using Supiroban, please consult your doctor, pharmacist or other health care professionals for advice.

Supiroban Ointment is not suitable for :

- Use in the eye
- Use in the nose
- Use in conjunction with cannulae

Supiroban Ointment should be used with caution in patients with extensive burns or wounds because of the possibility of macrogol toxicity i.e. toxicity due to one of the inactive ingredients of Supiroban.

(iv) Interactions

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

Do not start any new prescription or non-prescription medicines or supplements, unless you check with your doctor first.

If you are taking / using medicines on a regular basis, using Supiroban at the same time with another medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professionals for advice.

Instructions on how to use Supiroban Ointment

Apply to affected areas two to three times a day.

A small quantity of Supiroban Ointment should be applied to cover the affected area. The treated area may be covered by a dressing.

Do not share medicines prescribed for you with any other person.

Side effects

Supiroban Ointment may cause the following side effects:
Burning, stinging, dryness, skin irritations.

In the event of local irritation to the skin, treatment should be discontinued; the product should be rinsed off. Consult your doctor, pharmacist or other healthcare professionals for an appropriate alternative therapy for the infection.

Tell your doctor if you are concerned about any side effects you experience.

Not all side-effects reported for Supiroban are included in this leaflet. Should your general health worsen while using Supiroban, please consult your doctor, pharmacist or other health care professionals for advice.

Storage and disposal information

Store Supiroban Ointment at room temperature (at or below 25°C).
Do not refrigerate.

STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN.

Presentation

Supiroban Ointment is available in a latex, aluminium (not lacquered), collapsible tube with cap. The tube contains 14 g, 15 g or 50 g Ointment.

Identification

A white, translucent water miscible ointment.

Registration Number

43/20.1.6/0680

Namibia Reg. No. 11/20.1.6/0213

Name and Business address of the holder of the Certificate of Registration

Glenmark Pharmaceuticals South Africa (Pty) Ltd
Unit 7/8 York House
Tybalt Place, 185 Howic Close
Waterfall Office Park
Bekker Street
VORNA VALLEY

Date of Publication of the Package Insert
4 March 2011

320 mm

Scheduling status: S2

Proprietary Name and Dosage Form:

SUPIROBAN OINTMENT

glenmark

COMPOSITION

Mupirocin ointment	20mg/g

PHARMACOLOGICAL CLASSIFICATION

A. 20.1.6 Topical Antibiotics

PHARMACOLOGICAL ACTION

Pharmacological Properties

Mupurocin is an antibiotic produced through fermentation of *Pseudomonas fluorecense* and inhibits bacterial protein synthesis by binding to bacterial isoleucyl t-RNA synthetase.

Mupirocin has bacteriostatic properties at minimum inhibitory concentrations and bacterecidal properties at the higher concentrations reached when applied locally.

Following intravenous or oral administration, mupirocin is rapidly metabolised to the inactive monic acid.

Activity:
Mupirocin shows *in vivo* activity against *Staphylococcus aureus* (including methicillin resistant strains), S. epidermidis and beta haemolytic *Streptococcus* species.

PHARMACOKINETICS:

Absorption:
Mupurocin is poorly absorbed (less than 0.24 %) through intact human skin. However, if it is absorbed (e.g. through broken / diseased skin) or it is given systemically, it is metabolised to the microbiologically inactive metabolite monic acid and rapidly excreted.

Excretion:
Mupirocin is rapidly eliminated from the body by metabolism to its inactive metabolite monic acid which is excreted mainly by the kidney (90 %).

INDICATIONS

Supiroban Ointment is indicated for the topical treatment of primary and secondary bacterial skin infections caused by *Staphylococcus aureus* and other susceptible organisms.

Primary Skin Infection:
Impetigo, follicullitis, furunculosis and ecthyma

Secondary Infections:
Infected dermatoses e.g. infected eczema. Infected traumatic lesions e.g. abrasions, insect bites, minor (not requiring hospitalization) wounds and burns.

Prophylaxis:
Supiroban may be used to avoid bacterial contamination of small wounds, incisions and other clean lesions, and to prevent infection of abrasions and small cuts and wounds.

CONTRA-INDICATIONS

Supiroban Ointment is not indicated for the treatment of skin lesions infected with Pseudomonas aeruginosa.

Supiroban Ointment should not be used by patients with a history of hypersensitivity to any of its constituents.

WARNINGS

Supiroban ointment is not suitable for:

- Ophthalmic use
- Intranasal use
- Use in conjunction with cannulae.
- At the site of central venous cannulation.

Avoid contact with eyes. If contaminated, the eyes should be thoroughly irrigated with water until the ointment residues have been removed.

Supiroban should be used with caution in patients with extensive burns or wounds because of the possibility of macrogol toxicity.

Care is required in patients with renal impairment.

DOSAGE AND DIRECTIONS FOR USE

Adults, children, elderly:
Two to three times a day for up to 10 days, depending on the response.

Renal impairment:
See "Warnings".

Method of administration:
A small quantity of Supiroban ointment should be applied to cover the affected area. The treated area may be covered by a dressing. Any product remaining at the end of treatment should be discarded.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

Local reactions such as burning, stinging and itching may occur after application to the skin.

Erythema, dryness and itching have been reported less frequently.

Systemic allergic reactions with Supiroban Ointment may occur.

In the event of a possible hypersensitivity reaction or severe local irritation occurring with use of Supiroban Ointment, treatment should be discontinued, the product should be rinsed off and appropriate alternative therapy for the infection instituted.

Prolonged or irregular use may result in overgrowth of non-susceptible strains of *S. aureus* and other organisms.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

See Side Effects.

Treatment is symptomatic and supportive

IDENTIFICATION

A white, translucent water miscible ointment

PRESENTATION

Supiroban Ointment is available in a latex, aluminium (not lacquered), collapsible tube with cap. The tube contains 14 g, 15 g or 50 g Ointment.

STORAGE INSTRUCTIONS

Store at or below 25°C.

Do not refrigerate

KEEP OUT OF THE REACH OF CHILDREN.

Registration Number

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PE20987 **ZA/NA**

150 mm

SAME SIZE ARTWORK
LEAFLET SIZE : 150 mm x 320 mm

Skeduleringstatus: S2

Eiendomsnaam en Doseervorm:

SUPIROBAN SALF

Glenmark

Die Samestelling van die Medisyne

Die aktiewe bestanddeel (medisyne) bevat in
Supiroban Salf is mupirosien. 1 g van die salf bevat 20 mg mupirosien.

Supiroban Salf bevat ook die volgende onaktiewe rou materiale:

- Poliëtileenglikol 350
- Poliëtileenglikol 400

Indikasies en Gebruik
Waarvoor word Supiroban Salf gebruik?

Supiroban Salf word aangedui vir die topikale behandeling van primêre en sekondêre velinfeksies.

Supiroban Salf kan gebruik word om bakteriële besmetting van klein wonde, snye en ander skoon letsels te vermy, en om infeksie van skaafwonde en klein snye en wonde te verhoed.

Instruksies voordat Supiroban salf aangewend word
(i) Kontra-indikasies (Wie behoort nie Supiroban Salf te gebruik nie)

Moenie Supiroban Salf gebruik indien jy vir mupirosien (die aktiewe bestanddeel in Supiroban Salf) of die onaktiewe bestanddele allergies is nie. Verwys asseblief na die lys onaktiewe bestanddele hierbo.

Moenie Supiroban Salf gebruik om velletsels wat geïnfekteer is met 'n soort bakterie wat *Pseudomonas aeruginosa* genoem word, te behandel nie.

(ii) Voorsorgmaatreëls en (iii) Waarskuwings

Vertel jou dokter oor enige medisyne wat jy tans gebruik wat jy met of sonder voorskrif bekom het, insluitend natuurlike en kruiemedisyne. Vertel jou dokter indien jy:

- Ooit nierprobleme gehad het
- Swanger is of beplan om swanger te word of jou baba borsvoed terwyl jy Supiroban gebruik. Raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktisyns vir advies.

Supiroban Salf is nie geskik vir:

- Gebruik in die oog
- Gebruik in die neus
- Gebruik saam met kannules

Supiroban salf behoort met omsigtigheid gebruik te word in pasiënte met uitgebreide brandwonde of wonde as gevolg van die moontlikheid van makrogoltoksisiteit, d.i. toksisiteit veroorsaak deur een van die onaktiewe bestanddele van Supiroban.

(iv) Interaksies

Moenie Supiroban Salf met ander preparate meng nie omdat daar 'n risiko van verdunning bestaan, wat verlaging van die antibakteriële aktiwiteit en potensiële verlies aan stabiliteit van Supiroban salf veroorsaak.

Moenie enige nuwe voorskrif of nie-voorskrif medisyne of supplemente begin, tensy jy eers met jou dokter gesels het nie.

Indien jy medisyne gereeld neem/gebruik, mag die gelyktydige gebruik van Supiroban saam met 'n ander medisyne ongewenste interaksies veroorsaak. Raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktisyns vir advies.

Instruksies oor hoe om Supiroban Salf te gebruik:

Wend aan op geaffekteerde gebiede twee tot drie keer per dag.

'n Klein hoeveelheid Supiroban Salf behoort aangewend te word om die geaffekteerde gebied te bedek. Die behandelde gebied kan met 'n verband bedek word.

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Newe-effekte

Supiroban Salf mag die volgende newe-effekte veroorsaak:
Branderigheid, prikkeling, droogheid, velirritasies.

In geval van plaaslike irritasie van die vel, moet behandeling gestaak word; die produk moet afgespoel word. Raadpleeg jou dokter, apteker of ander gesondheidsorgpraktisyns vir toepaslike alternatiewe terapie vir die infeksie.

Vertel jou dokter daarvan as jy bekommerd is oor enige newe-effekte wat jy mag ondervind.

Nie al die newe-effekte wat vir Supiroban aangemeld is, word in hierdie brosjure ingesluit nie. Indien jou algemene gesondheid sou agteruitgaan terwyl jy Supiroban gebruik, moet jy asseblief jou dokter, apteker of ander gesondheidsorgpraktisyns vir advies raadpleeg.

Instruksies oor opberging en wegdoening

Bewaar Supiroban Salf by kamertemperatuur (by of onder 25°C).
Moenie in die yskas bewaar nie.

BEWAAR ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.

Aanbieding

Supiroban Salf is beskikbaar in 'n lateks, aluminium (nie vernis nie) opvoubare buis met 'n dop. Die buise bevat 14 g, 15 g of 50 g salf.

Identifikasie

'n Wit, deurskynende water-mengbare salf

Registrasienommer

43/20.1.6/0680

Namibia Reg. No. 11/20.1.6/0213

Naam en Besigheidsadres van die houer van die Sertifikaat van Registrasie

Glenmark Pharmaceuticals South Africa (Pty) Ltd
Unit 7/8 York House
Tybalt Place, 185 Howick Close
Waterfall Office Park
Bekker Street
VORNA VALLEY

Datum van Publikasie van die Pasiëntinligtingsbrosjure
4 March 2011

320 mm

Skeduleringstatus: S2

Eiendomsnaam en Doseervorm:

SUPIROBAN SALF

Glenmark

SAMESTELLING

Mupirosien salf 20mg/g

FARMAKOLOGIESE KLASSIFIKASIE

A.20.1.6 Topikale Antibiotika

FARMAKOLOGIESE WERKING

Farmakologiese Eienskappe

Mupirosien is 'n antibiotikum wat deur fermentasie van *Pseudomonas fluorescens* geproduseer word en dit inhibeer bakteriële proteïensintese deur binding aan bakteriële isoleusiel t-RNS-sintetase.

Mupirosien besit bakteriostatiese eienskappe teen minimum inhibitoriese konsentrasies en bakteriedodende eienskappe teen die hoër konsentrasies wat bereik word as dit plaaslik aangewend word.

Na intraveneuse of orale toediening, word mupirosien vinnig gemetaboliseer na die onaktiewe moniese suur.

Aktiwiteit:

Mupirosien toon *in vivo* aktiwiteit teen *Staphylococcus aureus* (insluitend metisillien-weerstandige stamme), *S. epidermidis* en beta-hemolitiese *Streptococcus* spesies.

FARMAKOKINETIKA:

Absorpsie:

Mupirosien word swak geabsorbeer (minder as 0.24%) deur intakte menslike vel. As dit egter geabsorbeer word (bv. deur beskadigde/siek vel) of indien dit sistemies toegedien word, word dit gemetaboliseer na die mikrobiologies onaktiewe metaboliet moniese suur en vinnig uigeskei.

Uitskeiding:
Mupirosien word vinnig uit die liggaam geëlimineer deur metabolisme na sy onaktiewe metaboliet moniese suur, wat hoofsaaklik deur die nier (90%) uitgeskei word.

INDIKASIES

Supiroban Salf word aangedui vir die topikale behandeling van primêre en sekondêre bakteriële velinfeksies veroorsaak deur *Staphylococcus aureus* en ander vatbare organismes.

Primêre Velinfeksie:
Impetigo, follikulitis, furunkulose en ektima

Sekondêre Infeksies:
Geïnfekteerde dermatoses, bv. geïnfekteerde ekseem. Geïnfekteerde troumatiese letsels, bv. skaafwonde, insekbyte, minder ernstige wonde en brandwonde (wat nie hospitalisasie vereis nie).

Profilakse:
Supiroban kan gebruik word om bakteriële besmetting van klein wonde, snye en ander skoon letsels te vermy, en om infeksie van skaafwonde en klein snye en wonde te verhoed.

KONTRA-INDIKASIES

Supiroban Salf word nie aangedui vir die behandeling van velletsels wat met *Pseudomonas aeruginosa* geïnfekteer is nie.

Supiroban Salf behoort nie deur pasiënte met 'n geskiedenis van hipersensitiwiteit teenoor enigeen van sy bestanddele gebruik te word nie.

WAARSKUWINGS

Supiroban Salf is nie geskik vir:

- Oftalmiese gebruik
- Intranasale gebruik
- Gebruik saam met kannules
- Op die plek waar 'n sentrale veneuse kannule geplaas word.

Vermy kontak met die oë. Indien die oë besmet word, moet dit deeglik met water gespoel word totdat die oorblyfsels van die salf verwyder is.

Supiroban behoort met omsigtigheid gebruik te word in pasiënte met uitgebreide brandwonde of wonde as gevolg van die moontlikheid van makrogoltoksisiteit.

Sorg is nodig by pasiënte met nierinkorting.

DOSIS EN GEBRUIKSAANWYSINGS

Volwassenes, kinders, bejaardes:
Twee tot drie keer per dag vir so lank as 10 dae, afhangende van die reaksie.

Nierinkorting:
Sien "Waarskuwings".

Metode van toediening:
'n Klein hoeveelheid Supiroban salf behoort aangewend te word om die geaffekteerde gebied te bedek. Die behandelde gebied kan met 'n verband bedek word. Enige produk wat oorbly aan die einde van behandeling behoort weggegooi te word.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS

Plaaslike reaksies soos branderigheid, prikkeling en jeuk mag na aanwending op die vel voorkom.

Eriteem, droogheid en jeuk is minder dikwels aangemeld.

Sistemiese allergiese reaksies mag met Supiroban Salf voorkom.

In geval van 'n hipersensitiwiteitsreaksie of ernstige plaaslike irritasie wat moontlik mag voorkom met die gebruik van Supiroban Salf, moet behandeling gestaak, die produk afgespoel en toepaslike alternatiewe terapie vir die infeksie ingestel word.

Langdurige of ongereelde gebruik mag oormatige groei van nie-vatbare stamme van *S. aureus* en ander organismes veroorsaak.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Sien Newe-effekte.
Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE

'n Wit, deurskynende water-mengbare salf

AANBIEDING

Supiroban Salf is beskikbaar in 'n lateks, aluminium (nie vernis nie) opvoubare buis met 'n dop. Die buise bevat 14 g, 15 g of 50 g salf.

BEWARINGSINSTRUKSIES

Bewaar teen of benede 25°C.

Moenie in die yskas bewaar nie.

HOU BUITE BEREIK VAN KINDERS.

Registrasienommer

43/20.1.6/0680

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VORNA VALLEY

Datum van Publikasie van die Voubiljet
4 March 2011

PE20987 **ZA/NA**

20 mm

150 mm

ICONGRAPHICS CODE: E11516

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