

SAP WORK INFORMATION:		440022 P3-2020 Trimycin® H ointment 1 g honey 55 CDS	
<input type="checkbox"/> NEW	<input type="checkbox"/> EXISTING	Form No.	355-33
Old FGS&K Code	115692	PMS No.	PMS-115692-02
New FGS&K Code		Applica No.	N/A
Existing Barcode	N/A	Dimension	140 x 98 mm
New Barcode		Reason For Revision	Update and CDS
Existing PM Code			
Required Reference Checklist:			
<input type="checkbox"/> CDS/CDS Approval of country	<input type="checkbox"/> PMS	<input type="checkbox"/> White Sheet	<input type="checkbox"/> Superseded Anterior
<input type="checkbox"/> Change Control	<input type="checkbox"/> FDA Approved Packaging Material	<input type="checkbox"/> Knifed-edge or PL Guide	<input type="checkbox"/> Code Updated in SAP

UNILAB

Hydrocortisone + Bacitracin + Polymyxin B Sulfate + Neomycin

Trimycin®-H Ointment

TOPICAL ANTIBACTERIAL / CORTICOSTEROID

FORMULATION

Each gram ointment contains:

Hydrocortisone 10 mg
Bacitracin 200 units
Polymyxin B sulfate 4000 units
Neomycin (as sulfate) 3 mg
In an inert petrolatum base

PRODUCT DESCRIPTION

Hydrocortisone + Bacitracin + Polymyxin B Sulfate + Neomycin (Trimycin®-H) is a snow white to off-white homogeneous ointment with a faint characteristic odor.

WHAT IS IN THE MEDICINE?

The medicine contains hydrocortisone, a mild topical corticosteroid that can relieve itch and reduce inflammation associated with various skin conditions. Since some corticosteroid-responsive skin conditions may also become infected, this medicine also contains the antibacterial agents, bacitracin, polymyxin B sulfate and neomycin. The combination of these three topical antibacterials is more effective than when used singly since together it gives better antibacterial coverage and affects different types of bacteria responsible for various skin infections.

STRENGTH OF THE MEDICINE

Please see formulation.

WHAT IS THE MEDICINE USED FOR?

This medicine is used for the relief of itch and inflammation associated with a variety of steroid-responsive skin conditions including allergies, eczema, insect bites, and minor burns where bacterial infection is present or likely to occur.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Wash hands before and after each application unless the medicine is used to treat a hand condition.

- Clean the affected and adjacent area with a mild soap and water.
- Rinse thoroughly and pat dry.
- Apply a thin layer over the affected area 1 to 3 times daily, or as directed by a doctor.

WHEN SHOULD YOU NOT USE THIS MEDICINE?

- If you are allergic to any component of the product.
- Do not use over extensive areas of broken skin.
- Not for use in the eyes or in the external ear canal if the eardrum is perforated.
- Do not use in tuberculous, fungal, or viral (e.g., herpes simplex, chickenpox) lesions of the skin.
- Do not use in patients with myasthenia gravis (a disease characterized by grave muscle weakness).

UNDESIRABLE EFFECTS

Hydrocortisone

Hydrocortisone is a mild steroid and is less likely to cause adverse effects than more potent ones. Undesirable effects are more likely to occur with use over large skin areas (children may absorb proportionally larger amounts of topical corticosteroids), or on broken skin, use of dressings that prevent air from circulating to the area being treated (e.g., plastic bandages, diapers), and with prolonged use.

The following local effects have been reported with use of topical corticosteroids: burning, itching, irritation, dryness, folliculitis (inflammation of the hair follicles), hypertrichosis (excessive hair growth), acne-like eruptions, hypopigmentation (decreased skin color), perioral dermatitis (inflammation around or near the mouth), allergic contact dermatitis, maceration (softening or soggy skin) of the skin, secondary infection, atrophy ("thinning" of the skin), striae (stretch marks), miliaria (prickly heat or heat rash).

Bacitracin

May rarely cause rashes and anaphylactoid reactions (severe allergic reactions).

Polymyxin B sulfate

Rare cases of allergic reactions [e.g., rashes, fever and bronchospasm (narrowing of airways)] have been reported.

Neomycin

- Rare allergic reactions such as rashes, burning, redness, inflammation, contact dermatitis, and urticaria ("hives" or itchy, swollen, red areas of the skin) have been reported.
- Rarely, patients may experience ototoxicity (permanent partial or total deafness), nephrotoxicity (kidney damage) and neuromuscular blockade following topical use of neomycin. The risk of these undesirable effects are increased with prolonged use; in patients who use the medicine over extensive areas of broken skin, burns, skin ulcer; and in patients with kidney disease or hearing impairment.

- Death due to anaphylaxis has occurred rarely after topical application of neomycin.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE USING THIS MEDICINE?

Tell the doctor if you are using the following medicines:

- Other topical corticosteroids (e.g., betamethasone, clobetasol, fluticasone, etc.)
- Other antibiotics:
 - The possibility of undesirable effects may increase when neomycin is applied topically together with aminoglycosides (e.g., amikacin, gentamycin and tobramycin).

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

Just apply the missed dose if still needed for the particular condition being treated and then continue with your regular dosing schedule. Do not double the dose.

SIGNS AND SYMPTOMS OF OVERDOSAGE

The use of large doses of topical hydrocortisone + bacitracin + polymyxin B sulfate + neomycin may lead to ototoxicity, nephrotoxicity or neuromuscular blockade [see **Undesirable Effects**].

However, when used as recommended, an overdose of topical hydrocortisone + bacitracin + polymyxin B sulfate + neomycin is unlikely to occur.

WHAT TO DO IF YOU HAVE USED MORE THAN THE RECOMMENDED DOSAGE?

If you have used more than the recommended dosage, or in case of accidental swallowing, seek medical help.

CARE THAT SHOULD BE TAKEN WHEN USING THIS MEDICINE

- For external use on the skin only.
- Do not use in the eyes and ears. If ointment comes in contact with these areas, rinse out promptly and thoroughly with water.
- Avoid contact with the eyelids or skin near the eyes because of the risk of corticosteroid-induced glaucoma (increased pressure inside the eye that causes visual problems), especially with prolonged use.
- Do not use on the face, underarms, groin areas, and genitalia unless directed by a doctor.
- Do not use in the treatment of diaper rash.
- Treated skin area should not be bandaged, or otherwise wrapped or covered, unless directed by a doctor.
- Do not use for more than 7 days, unless directed by a doctor.
- With prolonged use, this medicine may result in excessive growth of non-susceptible organisms including fungi.
- Allergic cross-reactions may occur which could prevent the use of any or all of the aminoglycosides for the treatment of future infections.
- Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

- Before using this medicine as topical treatment of deep or puncture wounds, animal bites or serious burns. These conditions may result in more severe or serious infections for which this medicine is not recommended.
- If you are using other medicines on your skin.
- If pregnant or breastfeeding.
- Before use in children.
- If symptoms persist or conditions worsen.
- If undesirable effects are experienced, stop use and consult a doctor.

HOW SHOULD YOU KEEP THIS MEDICINE?

- Keep container tightly closed.
- Keep the product out of sight and reach of children.
- Store at temperatures not exceeding 30°C.
- Protect from light.

ADVERSE DRUG REACTION REPORTING STATEMENT

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov/ph AND Unilab at +632-8-UNILAB-1 (+632-8-864522-1) for Metro Manila or toll-free +1-800-10-UNILAB-1 for provinces, or e-mail productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

AVAILABILITY

Aluminum Tube x 5g (Box of 1's)

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DR-937

Manufactured by ASIAN ANTIBIOTICS, INC.
No. 130 Pioneer Street, Mandaluyong City
Philippines for **UNILAB, Inc.**
No. 66 United Street, Mandaluyong City
Metro Manila, Philippines

Reg. IPOPHIL

P300000030390

UNILAB Consumer Care

8-UNILAB-1
8 - 8 6 4 5 2 2 - 1

Provincial Toll Free: 1-800-10-8645221

Email: info@unilab.com.ph

Website: www.unilab.com.ph



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