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U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND

Expanded Access Treatment Protocol for Uncomplicated Cutaneous Leishmaniasis

Topical Paromomycin Cream is Available to Treat Cutaneous Leishmaniasis in Department of Defense Healthcare Beneficiaries

This expanded access treatment protocol now makes topical paromomycin cream available for the treatment of Department of Defense (DoD) healthcare beneficiaries with uncomplicated cutaneous leishmaniasis (CL).

- There is currently no standard regimen for the treatment of CL in the United States.
- Local therapies may include cryotherapy with liquid nitrogen, heat treatment, or off label compounded paromomycin ointment.
- Oral systemic treatment may include the off label use of fluconazole for uncomplicated CL, which has modest activity against the disease but is well tolerated, and Miltefosine, which is currently the only drug approved by the U.S. Food and Drug Administration (FDA) to treat CL in the U.S. caused by *L. braziliensis*, *L. guyanensis*, and *L. panamensis*. The safety and efficacy of Miltefosine in the pediatric population has not been established.
- Parenteral treatment options include investigational antimonials, administered under an Investigational New Drug (IND) protocol, and liposomal amphotericin B, which is FDA approved for visceral leishmaniasis.



Cutaneous Leishmaniasis is a parasitic disease of the skin, endemic in 98 countries and territories throughout the world, primarily in the Middle East and North Africa, and Central and South America. CL causes potentially disfiguring skin ulcers that can persist for months or years if left untreated.

Incidence of Cutaneous Leishmaniasis in United States Service Members

Over 3,100 cases of CL have been confirmed in U.S. military Service Members since June 2003, and approximately 50-100 cases continue to be confirmed each year at the Leishmania Diagnostic Laboratory at the Walter Reed Army Institute of Research.

Paromomycin Cream and the New Treatment Protocol

Paromomycin has been used in various dosage forms to treat leishmaniasis for many years, and topical treatment with paromomycin is recommended by the World Health Organization as a first-line treatment for uncomplicated CL. The U.S. Army's paromomycin cream is a third generation topical paromomycin formulation in a new cream base that aids drug penetration into the CL ulcer. Paromomycin are in the class of medications known as aminoglycoside antibiotics.

The FDA approved IND application # 50098, which makes this new class of antileishmanial medication, paromomycin cream, available in the United States for the first time.

The U.S. Army Medical Materiel Development Activity (USAMMDA) has been conducting studies in several countries using paromomycin, with the largest of these studies to date completed in Tunisia in 2011 (Ben Salah et.al., N Engl J Med 368:6, 524). USAMMDA is in a position to make this medication available to DoD healthcare beneficiaries.

The paromomycin cream is available only to DoD healthcare beneficiaries of any age who qualify for topical treatment because they have:



Tubes of paromomycin topical cream are shown here.

- At least one CL lesion with a positive diagnosis for Leishmaniasis.
- Lesions(s) in a location amenable to topical treatment.
- No evidence of involvement of the mucosa (mucous membranes in the nose, mouth, and/or throat).
- No other clinically significant condition that precludes treatment.

The drug will be sent to treating providers at DoD healthcare facilities, upon request to the USAMMDA Treatment Protocol Team and confirmation of patient eligibility.

How to Obtain Paromomycin Cream

To enroll a patient with uncomplicated CL in this treatment protocol, or to consult with the Investigator team on potential eligibility of a patient, contact the USAMMDA CL Treatment Protocol Team at:

usarmy.detrick.medcom-usammda.list.leishmania-tx-protocol@mail.mil