

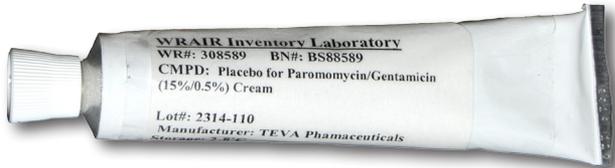


**USAMMDA MISSION** is Develop and deliver quality medical solutions to protect, treat, and sustain the health of Our service members

## TOPICAL PAROMOMYCIN

A safe and effective topical therapy for cutaneous leishmaniasis (CL) remains a key gap in the repertoire of treatments available to

physicians throughout the world. The U.S. Army Medical Research and Materiel Command (USAMRMC) is developing Topical Paromomycin to fill that gap. This therapy will provide an easy-to-use option for U.S. service members that can be self-administered in a deployed setting, avoiding the need for evacuation from theater and treatment with toxic, systemic therapies. The World Health Organization has endorsed treatment with topical paromomycin formulations as first-line therapy for CL, and the USAMRMC Topical Paromomycin product is poised to be the first such solution for the broader worldwide community.



If approved by the U.S. Food and Drug Administration (FDA), Topical Paromomycin could provide an effective treatment option to caregivers to sustain service members and unit performance by:

- Providing a safe, effective, and simple treatment option for uncomplicated CL infection.
- Mitigating the psychological impact from the potential disfiguring disease.
- Minimizing lost duty time with a simplified treatment regimen (topical versus intravenous) which will allow Servicemember to self-treat while remaining close to their duty station.

The current treatment for CL in the United States and throughout the CL-endemic regions of the world requires intravenous or intralesional administration of toxic, heavy metal-based drugs (antimonials). In the United States, this is an investigational treatment that involves 10-20 days of daily IV infusions under close physician monitoring in a hospital. The current IV treatment has many undesirable side effects and toxicities, including vomiting, diarrhea, pancreatitis, elevated liver enzymes, and pulmonary edema (when exposed to higher doses). Systemic therapies are also quite expensive, and impose an enormous administrative and regulatory burden on U.S. providers. The current average cost per patient for hospitalization, treatment, and lost duty time is about \$35,000. This equates to over \$38 million for the 1,100 troops requiring treatment from 2003 to the present. More importantly, U.S. service members must currently leave their units and be evacuated to the United States to receive these treatments for CL. Not only does this impact the unit's overall readiness while service members are evacuated for treatment, but the cost of evacuation can be as high as \$500,000 per case depending on where the service member is deployed and the means used for evacuation.



Topical Paromomycin is being developed by the USAMRMC as a first-line therapy that may be easily used and self-administered. A safe and effective topical treatment would fill a critical gap in currently available treatment options, and relegate toxic, systemic therapy to only the more complicated forms of CL.

#### USAMMDA Contact

Product Manager  
301.619.6823

#### Development Partners

USAMMDA, WRAIR, WRNMMC,  
Institut Pasteur de Tunis, the Institut  
Pasteur-Paris, Gorgas Memorial  
Institute for Health Studies, Universidad  
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