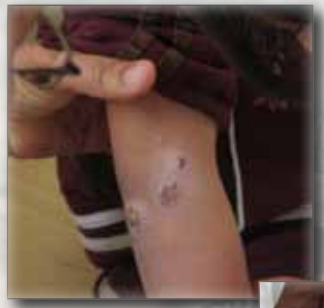
USAMMDA Mission

The USAMMDA **Mission** is to develop and manage medical materiel to protect and sustain the Warfighter on point for the Nation.



USAMMDA Vision

The USAMMDA **Vision** is to integrate with USAMRMC, Federal agencies, and the DoD, as part of the joint biomedical research and materiel community, to focus on delivering the best medical solutions for today and tomorrow.

Our products are an integral part of the DoD Force Health Protection Program, to include vaccines, drugs, and medical devices, to prevent, diagnose, and treat infectious diseases, combat-related casualties, and CBRNE threats.

Our products enhance far-forward medical care across the full spectrum of health care missions worldwide.

For more information about USAMMDA

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U.S. Army Medical Research and Materiel Command

Protect the Warrior, Sustain the Force

Updated: December 28, 2011

USAMMDA

U.S. Army Medical Materiel Development Activity

Developing Quality Medical Products for U.S. Forces

Topical Paromomycin

Topical therapy for the treatment of Cutaneous Leishmaniasis

Why 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. Servicemembers 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.

Product Development

Topical Paromomycin's United States and International development partners include: USAMMDA; Walter Reed Army Institute of Research (WRAIR); the Institut Pasteur de Tunis, the Institut Pasteur – Paris; the Gorgas Memorial Institute for Health Studies – Panama City, Panama; the Universidad Peruana Cayetano Heredia – Lima, Peru; the Naval Medical Research Detachment – Peru; and the Walter Reed National Military Medical Center (WRNMMC).

Benefits to the Warfighter

Topical Paromomycin will be an easy-to-use topical cream containing the antibiotics paromomycin and gentamicin. This product is under development as a self-administered treatment for uncomplicated Cutaneous Leishmaniasis (LEASH-ma-NIGH-a-sis).

CL is a serious parasitic disease caused by protozoan parasites. It is transmitted to humans through the bite of an infected sand fly in tropical and subtropical zones, including the Middle East. Although CL is usually a non-life threatening disease, it can be mutilating and disfiguring.

Nearly every U.S. Servicemember serving in the Middle East in support of Operation Enduring Freedom and Operation Iraqi Freedom is at risk of exposure to CL, as are Servicemembers who continue to be deployed to CL-endemic regions throughout the world. This disease has been a relatively common infection among deployed Servicemembers, with more than 3,000 confirmed cases since 2003.

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

A Key Addition to the CL "Toolkit"

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. Servicemembers 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 Servicemembers are evacuated for treatment, but the cost of evacuation can be as high as $500,000 per case depending on where the Servicemember 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.