

Cover Sheet

DATE: 26 August 2013

SUBJECT: Investigational Drug Available Directly
from CDC for the Treatment of Free-Living Ameba
Infections

INSTRUCTIONS:

REDISTRIBUTE AT YOUR DISCRETION. Share this
information with relevant SMEs or contacts (internal and
external) as you see fit.

For LOCAL HEALTH
DEPARTMENT reference only

DPHHS Subject Matter Resource for
more information regarding this HAN,
contact:

DPHHS CDCP
Epidemiology Section
1-406-444-0273

DPHHS Health Alert Hotline:
1-800-701-5769

DPHHS HAN Website:
www.han.mt.gov

**REMOVE THIS COVER SHEET BEFORE REDISTRIBUTING
AND REPLACE IT WITH YOUR OWN**

Please ensure that DPHHS is included on your HAN distribution list.

Categories of Health Alert Messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: provides important information for a specific incident or situation; may not require immediate action.

Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

Information Service: passes along low level priority messages that do not fit other HAN categories and are for informational purposes only.

Please call DPHHS to update contact information at 444-0919 or 444-6906

Information Sheet

Date: August 26, 2013

Subject: Investigational Drug Available Directly from CDC for the Treatment of Free-Living Ameba Infections (FLA)

Background: Rare FLA infections are severe and life threatening with mortality greater than 90% despite treatment. FLA is most common in southern tier states; however, FLA appears to only need warm water to survive. To decrease the FLA mortality rate, new treatment options have been researched. *Miltefosine* is a drug used to treat leishmaniasis and also has shown in vitro activity against FLA (1). As an investigational drug *Miltefosine* has not been readily available in the United States.

Information: the CDC has expanded access to *Miltefosine* because it has shown in vitro activity against FLA. *Miltefosine* is available directly from the CDC; however, it is still not readily available elsewhere in the United States.

Recommendations: Please see the attached CDC Information Advisory for more specific information. CDC recommends that clinicians who suspect they have a patient with FLA infection who could benefit from treatment with *Miltefosine* should contact CDC to consult. For more information: <http://www.cdc.gov/parasites/naegleria/general.html#howcommonenvironment>

This is an official
CDC HAN INFOService

Distributed via the CDC Health Alert Network
August 23, 2013, 11:30 ET (11:30 AM ET)
HANINFO-00354

Investigational Drug Available Directly from CDC for the Treatment of Free-Living Ameba Infections

Summary: CDC now has an expanded access investigational new drug (IND) protocol in effect with the Food and Drug Administration (FDA) to make miltefosine available directly from CDC to clinicians for treatment of free-living ameba (FLA) infections in the United States.

Background

Infections caused by FLA are severe and life-threatening. These infections include primary amebic meningoencephalitis (PAM) caused by *Naegleria fowleri** and granulomatous amebic encephalitis caused by *Balamuthia mandrillaris*† and *Acanthamoeba* species.§ Although several drugs have in vitro activity against FLA, mortality from these infections remains greater than 90% despite treatment with combinations of drugs.

Miltefosine is a drug used to treat leishmaniasis and also has shown in vitro activity against FLA (1), but as an investigational drug, it has not been readily available in the United States. With CDC assistance, however, miltefosine has been administered in combination with other drugs since 2009 for FLA infections as single-patient emergency use with permission from the Food and Drug Administration. Although the number of *B. mandrillaris* and *Acanthamoeba* species infections treated with a miltefosine-containing regimen is small, it appears that a miltefosine-containing treatment regimen does offer a survival advantage for these usually fatal infections (2). Miltefosine has not been used successfully to treat a *Naegleria* infection, but the length of time it has taken to import miltefosine from abroad has made timely treatment of fulminant *Naegleria* infections with miltefosine difficult.

CDC now has an expanded access IND protocol in effect with the Food and Drug Administration to make miltefosine available directly from CDC for treatment of FLA in the United States. The expanded access IND use of miltefosine for treatment of FLA is partly supported by 26 case reports of FLA infection from around the world during the period of 2008–2012 in which miltefosine was part of the treatment regimen (Unpublished data, Division of Foodborne, Waterborne, and Environmental Diseases, National Center for Emerging and Zoonotic Infectious Diseases, CDC, 2013). Miltefosine is generally well-tolerated, with gastrointestinal symptoms as the most commonly reported adverse effects.

Recommendation

Clinicians who suspect they have a patient with FLA infection who could benefit from treatment with miltefosine should contact CDC to consult with an FLA expert. See the **For More Information** section below for information on contacting a CDC FLA expert.

For More Information

- For diagnostic assistance, specimen collection guidance, specimen shipping instructions, treatment recommendations, and information on obtaining miltefosine from CDC, clinicians should contact the CDC Emergency Operations Center at 770-488-7100 to request to speak to an FLA expert.

- For more information on diagnostic assistance specimen collection guidance and specimen shipping instructions, see <http://www.cdc.gov/parasites/naegleria/diagnosis-hcp.html>.
- For *Naegleria fowleri* treatment recommendations, see <http://www.cdc.gov/parasites/naegleria/treatment-hcp.html>.
- For the *MMWR* Notice to Readers on this topic, see http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6233a4.htm?s_cid=mm6233a4_w.

References

1. Schuster FL, Guglielmo BJ, Visvesvara GS. In-vitro activity of miltefosine and voriconazole on clinical isolates of free-living amebas: *Balamuthia mandrillaris*, *Acanthamoeba* spp., and *Naegleria fowleri*. *J Eukaryot Microbiol* 2006;53:121–6.
2. Cope JR, Roy SL, Yoder JS, Beach MJ. Improved treatment of granulomatous amebic encephalitis and other infections caused by *Balamuthia mandrillaris* and *Acanthamoeba* species [Poster]. Presented at CSTE Annual Conference, Pasadena, CA, June 9–13, 2013. Available at <http://www.cste2.org/confpresentations/uploadedfiles/cste%202013%20miltefosine%20Poster%20final.pdf>.

Endnotes

- * Additional information available at <http://www.cdc.gov/parasites/naegleria>.
 † Additional information available at <http://www.cdc.gov/parasites/balamuthia>.
 § Additional information available at <http://www.cdc.gov/parasites/acanthamoeba>.

The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national, and international organizations.

Categories of Health Alert Network messages:

Health Alert Requires immediate action or attention; highest level of importance
Health Advisory May not require immediate action; provides important information for a specific incident or situation
Health Update Unlikely to require immediate action; provides updated information regarding an incident or situation
HAN Info Service Does not require immediate action; provides general public health information

##This message was distributed to state and local health officers, state and local epidemiologists, state and local laboratory directors, public information officers, HAN coordinators, and clinician organizations##