

Health Advisory:

Shortage of Erythromycin Ophthalmic Ointment for Prophylaxis of Ophthalmia Neonatorum

September 4, 2009

This document will be updated as new information becomes available. The current version can always be viewed at <http://www.dhss.mo.gov>

The Missouri Department of Health & Senior Services (DHSS) is now using 4 types of documents to provide important information to medical and public health professionals, and to other interested persons:

Health Alerts convey information of the highest level of importance which warrants immediate action or attention from Missouri health providers, emergency responders, public health agencies, and/or the public.

Health Advisories provide important information for a specific incident or situation, including that impacting neighboring states; may not require immediate action.

Health Guidances contain comprehensive information pertaining to a particular disease or condition, and include recommendations, guidelines, etc. endorsed by DHSS.

Health Updates provide new or updated information on an incident or situation; can also provide information to update a previously sent Health Alert, Health Advisory, or Health Guidance; unlikely to require immediate action.

Office of the Director
912 Wildwood
P.O. Box 570
Jefferson City, MO 65102
Telephone: (800) 392-0272
Fax: (573) 751-6041

Web site: <http://www.dhss.mo.gov>

Health Advisory
September 4, 2009

**FROM: MARGARET T. DONNELLY
DIRECTOR**

SUBJECT: Shortage of Erythromycin Ophthalmic Ointment for Prophylaxis of Ophthalmia Neonatorum

The Centers for Disease Control and Prevention (CDC) and the Missouri Department of Health and Senior Services (DHSS) have recently received reports of a shortage of erythromycin (0.5%) ophthalmic ointment. This Health Advisory provides guidance for obtaining supplies of erythromycin (0.5%) ophthalmic ointment during this shortage.

Erythromycin ophthalmic ointment is the recommended prophylaxis for ophthalmia neonatorum. Tetracycline ophthalmic ointment (1%) is also recommended for prophylaxis for ophthalmia neonatorum, but is no longer marketed in the U.S. Silver nitrate (1%), which was a recommended regimen in the 2002 STD Treatment Guidelines, is not available in the U.S.

CDC has been in contact with the U.S. Food and Drug Administration (FDA), which is aware of the shortage of erythromycin ophthalmic ointment and is working with the pharmaceutical companies to increase the supply of this product for neonatal prophylaxis use. The shortage is due to a change in manufacturers. Fera Pharmaceuticals recently acquired the rights to the product and is actively working to make erythromycin ophthalmic ointment available. Bausch and Lomb also manufactures erythromycin ophthalmic ointment and is working to increase production during this period of drug shortage.

FDA's Drug Shortages website has updated information regarding availability of erythromycin ophthalmic ointment. (<http://www.fda.gov/Drugs/DrugSafety/DrugShortages>)

To secure supplies, CDC recommends the following over the next several weeks:

1. Review your supplies of erythromycin ophthalmic ointment (0.5%) routinely.
2. Reserve current supplies of erythromycin ophthalmic ointment (0.5%) for neonatal prophylaxis use.
3. For normal replacement supplies, contact your wholesale distributor directly.
4. For severely low supplies (i.e., depletion within a week), contact your wholesale distributor or call Bausch and Lomb customer service at 1-800-323-0000 directly.
5. CDC is consulting with other experts to provide alternate recommendations for extreme situations where erythromycin ophthalmic ointment is not available. These recommendations are forthcoming. In the meantime, in circumstances where a recommended regimen is not available, mothers should be tested for chlamydia and gonorrhea prior to delivery, and results obtained as soon as possible. The 2006 STD Treatment Guidelines outline recommended prophylactic treatment for infants whose mothers have gonococcal infection and for management of infants born to mothers who have untreated chlamydia. Empiric treatment is recommended for infants exposed to gonorrhea (page 48)¹, while monitoring for development of symptoms prior to initiating treatment is recommended for infants exposed to chlamydia (page 42)². (<http://www.cdc.gov/std/treatment>)

DHSS encourages health care institutions to check with other hospitals in the area, as well as retail pharmacies, regarding local availability of erythromycin ophthalmic ointment. Hospitals experiencing shortages should consider using the 3.5 gm size erythromycin ophthalmic ointment if the 1 gm size is not available.

Please circulate this guidance to colleagues who may be affected by the shortage.

Contact the FDA drug shortage e-mail account (drugshortages@fda.hhs.gov) with additional inquiries about the shortage. Questions can also be directed to DHSS's Bureau of HIV, STD, and Hepatitis at 573/751-6439, or 800/392-0272 (24/7).

1. For gonorrhea: Ceftriaxone 25-50mg/kg IV or IM, not to exceed 125 mg, in a single dose.
2. For chlamydia: Erythromycin base or Ethylsuccinate 50mg/kg/day orally divided into 4 doses daily for 14 days.