

**From:** Missouri Department of Health and Senior Services  
**Through:** Kansas City, Missouri Health Department  
**KCHD HAN Number:** KC 029-09  
**Date:** September 11, 2009  
**Subject: Health Advisory and Update: 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)<sup>1</sup>, while monitoring for development of symptoms prior to initiating treatment is recommended for infants exposed to chlamydia (page 42)<sup>2</sup>. (<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](mailto: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).

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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.

UPDATE Issued 9/10/09

The Centers for Disease Control and Prevention (CDC) and the Missouri Department of Health and Senior Services (DHSS) recently received reports of a shortage of erythromycin (0.5%) ophthalmic ointment, which is the recommended prophylaxis for ophthalmia neonatorum. On September 4, 2009, DHSS issued a Health Advisory, entitled "Shortage of Erythromycin Ophthalmic Ointment for Prophylaxis of Ophthalmia Neonatorum", which contained guidance from CDC for responding to this situation ([http://www.dhss.mo.gov/BT\\_Response/HAd9-4-09.pdf](http://www.dhss.mo.gov/BT_Response/HAd9-4-09.pdf)).

CDC has now revised their guidance to include not only recommendations for securing supplies of erythromycin ophthalmic ointment, but also recommendations for the use of other ophthalmic solutions or ointments "for extreme situations where erythromycin ophthalmic ointment is not available." An alternative or additional approach provided in the guidance is to test the mother for gonorrhea and chlamydia prior to delivery in order to identify exposed infants. Empiric treatment is recommended for infants exposed to gonorrhea; monitoring for development of symptoms prior to initiating treatment is recommended for infants exposed to chlamydia. The revised CDC guidance is available at: <http://www.cdc.gov/std/treatment/2006/erythromycinOintmentShortage.htm>.

Additional changes to this guidance may occur in the future. Providers are strongly encouraged to periodically check CDC's STD Treatment Guidelines Web site at <http://www.cdc.gov/std/treatment/default.htm> for possible further revisions.

Contact the FDA drug shortage e-mail account ([drugshortages@fda.hhs.gov](mailto: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).