



August 31, 2009

Dear Colleague,

CDC has recently received reports of a shortage of erythromycin (0.5%) ophthalmic ointment. 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 United States. Silver nitrate (1%) which was a recommended regimen in the 2002 STD Treatment Guidelines is not available in the United States. The purpose of this letter is to provide guidance for obtaining supplies of erythromycin (0.5%) ophthalmic ointment during this shortage.

CDC has been in contact with the U.S. Food and Drug Administration (FDA). The FDA is aware of the shortage 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 are 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. The FDA's [Drug Shortages website](#) has information regarding availability of Erythromycin Ophthalmic Ointment and will be updated as new information becomes available. (<http://www.fda.gov/Drugs/DrugSafety/DrugShortages>)

To secure supplies, we recommend 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](#) outlines 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>)

Please circulate this guidance to colleagues who may be affected by the shortage. The CDC point of contact for these recommendations is Dr. Roxanne Barrow (RBarrow@cdc.gov). Contact the FDA drug shortage e-mail account (drugshortages@fda.hhs.gov) with additional inquiries about the shortage.

Sincerely,

/John M. Douglas, Jr. /

John M. Douglas Jr., MD, Director
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National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

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