



Sexually Transmitted Diseases

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CDC Guidance on Shortage of Erythromycin (0.5%) Ophthalmic Ointment - September 2009

Update October 7, 2009

FDA has received reports from a few locations of adverse events associated with use of gentamicin ophthalmic ointment as an alternative for prophylaxis of ophthalmia neonatorum, given the shortage of erythromycin ophthalmic ointment. The reports are related to the use of Gentak (Gentamicin Ophthalmic Ointment) 0.3%, Akorn, from several lots. The cases involve lid swelling and dermatitis, appearing a few days after ointment application. Most cases have been mild and have not required additional treatment. Some cases were more severe and were associated with blistering of the skin. The conjunctiva, orbital contents nor cornea were involved in any cases, and all cases resolved without complication. These adverse events are being investigated by the FDA. The probability of this dermatitis occurring cannot be reliably estimated at this time. There is anecdotal experience from a hospital where several cases were described, that wiping excess ointment off the eyelids seems associated with a milder reaction, when it occurs. Providers and hospitals should make efforts to obtain erythromycin ophthalmic ointment so that alternative preparations will not be needed. They can also consider the use of other alternatives such as AzaSite (Azithromycin Ophthalmic Solution) 1%, Inspire Pharmaceuticals. However, experts continue to regard gentamicin ophthalmic ointment as an acceptable alternative. Bausch and Lomb, the manufacturer of erythromycin ophthalmic ointment (0.5%, 1 gram tube), anticipates that sufficient quantity to meet full market demand will be available by the end of October. Providers should continue to report adverse events following administration of alternative methods of neonatal eye prophylaxis to [FDA MedWatch](#) (<http://www.fda.gov/Safety/MedWatch>).

Update September 25, 2009

Bausch & Lomb is releasing product for the 50 x 1 gm packaging configuration, with projections to meet demand in October 2009. All product manufactured in the 50 X 1 gram configuration will be allocated to all of Bausch & Lomb's established wholesalers and distributors. Fera Pharmaceuticals recently acquired the rights to manufacture this product and is actively working to make it available again. See the [FDA website](#) (<http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm>) for updated information.

CDC continues to work with the U.S. Food and Drug Administration (FDA) and other experts to provide updates regarding the shortage of Erythromycin Ophthalmic Ointment (0.5%). This page provides guidance on securing supplies and recommendations for preventing increases in the occurrence of ophthalmia neonatorum during the shortage.

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. Notify the FDA drug shortage e-mail account (drugshortages@fda.hhs.gov), if supplies are not available.

5. CDC has consulted with other experts about alternate recommendations for extreme situations where erythromycin ophthalmic ointment is not available. These recommendations are provided below.

If Erythromycin Ophthalmic Ointment (0.5%) is not available, we recommend the following:

1. Our experts indicate that AzaSite® (Azithromycin Ophthalmic Solution 1%, Inspire Pharmaceuticals) is an acceptable alternative, if Erythromycin Ophthalmic Ointment (0.5%) is not available.
 - a. There are no clinical data on efficacy of this product for the prophylaxis of ophthalmia neonatorum; the recommendation is made on the basis of available data on pharmacology and gonococcal microbiologic sensitivity.
 - b. AzaSite® is not FDA approved for this indication.
 - c. Use is recommended whether the infant is delivered vaginally or by cesarean section.
 - d. The recommend dose is 1-2 drops placed in the conjunctival sac of each eye, taking care to not touch the applicator tip to the infant. Because this is a solution rather than an ointment, it is important to assure that drops are placed properly. Consider a two person administration approach— one to hold the eye lids open and the other to administer the medication.
2. The following are acceptable alternatives if neither AzaSite® (Azithromycin Ophthalmic Solution 1%, Inspire Pharmaceuticals) nor Erythromycin Ophthalmic Ointment (0.5%) is available:
 - a. Gentak® (Gentamicin Ophthalmic Ointment 0.3%, Akorn) or
 - b. Tobrex® (Tobramycin Ophthalmic Ointment 0.3%, Alcon Laboratories).
 - c. If none of these preparations are available, a fluoroquinolone ophthalmic ointment: Ciloxan® (Ciprofloxacin Ophthalmic Ointment 0.3%, Alcon Laboratories) can be used, but this is a less suitable alternative given data on possible gonococcal antimicrobial resistance.
 - d. Caveats “a” through “c” outlined in item 1 above also apply for these alternatives.
3. Betadine (povidone iodine) is not recommended primarily because of the potential confusion with and possible use of the more familiar detergent formulation, which could be quite harmful.
4. Since efficacy data are not available for any of the suggested alternate regimens, providers should be alert to the possibility of failure of prophylaxis;
 - a. Providers are strongly encouraged to follow the AAP recommendation that infants be seen for their first postnatal office visit 48-72 hours post discharge from the hospital. (PEDIATRICS Vol. 120 No. 6 December 2007, pp. 1376), and to examine closely for ophthalmia neonatorum.
 - b. Testing for *N. gonorrhoeae* should be included for all infants who present with ophthalmia neonatorum, and reports of prophylaxis failure sent to local health departments and to CDC.

5. An alternative or additional approach is to test mother for gonorrhea and chlamydia prior to delivery, with prompt follow-up. 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. Screening mothers will allow providers to identify infants with known exposure (www.cdc.gov/std/treatment).

- **CDC point of contact:** Dr. Roxanne Barrow (RBarrow@cdc.gov).
- **FDA Resources:**
 - [FDA - Drug Shortages](http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm)
<http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>
 - [FDA - Erythromycin Ophthalmic Ointment Shortage](http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm181113.htm)
<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm181113.htm>
 - FDA drug shortage e-mail account: (drugshortages@fda.hhs.gov) for additional inquiries about the shortage.

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

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