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State of California—Health and Human Services Agency
California Department of Public Health



ARNOLD SCHWARZENEGGER
Governor

September 8, 2009

AFL 09-36

TO: General Acute Care Hospitals
Alternative Birthing Clinics
Primary Care Clinics
Special Hospitals

SUBJECT: Prophylaxis for Ophthalmia Neonatorum During Erythromycin (0.5%)
Ophthalmic Ointment Shortage

The recommended prophylaxis for ophthalmia neonatorum, erythromycin (0.5%) ophthalmic ointment, has been identified as being in short supply by the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA). A new CDC web page has been created to provide updates on securing supplies and recommendations for preventing increases in ophthalmia neonatorum during the shortage <http://www.cdc.gov/std/treatment/2006/erythromycinOintmentShortage.htm>.

Recommendations as of September 4, 2009 for managing ophthalmia neonatorum prophylaxis during the shortage are outlined below. Also provided is a review of the guidelines for chlamydia and gonorrhea screening in pregnancy as well as empiric management for exposed neonates. This shortage can also serve to underscore the importance of screening during pregnancy and timely treatment prior to delivery as they are the most effective measures to prevent ophthalmia neonatorum .

Secure supplies:

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.
 - Health care providers should check with their pharmacies to ensure they are aware of the shortage, are monitoring supplies and only using erythromycin ophthalmic ointment (0.5%) for newborns.

3. 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.

Status of erythromycin (0.5%) ophthalmic ointment production and availability:

We have received reports that Bausch and Lomb has increased production and are shipping as they manufacture to three wholesalers, AmerisourceBergen, Cardinal Health and McKesson. Since Bausch and Lomb does not sell directly to hospitals, it would be better to call one of these three wholesalers. As of today, none of the wholesalers currently have it in stock. Bausch and Lomb reports they anticipate shipping to wholesalers in mid September and they expect it will take 30 to 60 days to meet market demand.

AmerisourceBergen
Valencia: (800) 648-4026
Corona: (800) 252-8773
Sacramento: (800) 635-4907

Cardinal Health
(614) 757-5000

McKesson
(800) 482-3784

Alternatives if erythromycin (0.5%) ophthalmic ointment is unavailable

1. AzaSite® (Azithromycin Ophthalmic Solution 1%, Inspire Pharmaceuticals) is the CDC recommended substitute.
 - Recommend dose is 1-2 drops placed in the conjunctival sac of each eye. Because this is a solution rather than an ointment, it is important 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. Use is recommended whether the infant is delivered vaginally or by cesarean section.
2. Other alternatives include: Gentak® (Gentamicin Ophthalmic Ointment 0.3%, Akorn) or Tobrex® (Tobramycin Ophthalmic Ointment 0.3%, Alcon Laboratories).
3. California laws do not prohibit the use of these alternatives.
4. Since efficacy data are not available for any of the alternate regimens, providers should be alert to the possibility of failure of prophylaxis and follow the AAP recommendation that infants be seen for their first postnatal office visit 48-72 hours post discharge from the hospital. At this visit, examine closely for ophthalmia neonatorum. Testing for *N. gonorrhoeae* should be included for all

infants with ophthalmia neonatorum and reports of prophylaxis failure sent to local health departments and to CDC.

5. Tetracycline ophthalmic ointment and silver nitrate are no longer available in the U.S.
6. Betadine (povidone iodine) is not recommended.

California Law regarding ophthalmia neonatorum prophylaxis and treatment

Under California law (Business and Professions Code, Section 551), it is the duty of any physician, surgeon, obstetrician, midwife, nurse, maternity home or hospital of any nature, parent, relative, and any person or persons attendant upon, or assisting in any way whatsoever, either the mother or child, or both, at childbirth, to treat both eyes of the infant within two hours after birth with a prophylactic efficient treatment, and in all cases where the child develops within two weeks after its birth ophthalmia neonatorum, and such person knows it to exist, to report the case within 24 hours after knowledge, in such form as the department directs, to the local health officer of the county or city within which the mother of any such infant resides.

- For infants exposed to untreated gonorrhea, empiric treatment is recommended: Ceftriaxone 25-50mg/kg IV or IM, not to exceed 125 mg, in a single dose
- For infants exposed to untreated chlamydia, monitoring for development of symptoms prior to initiating treatment is recommended. Treatment includes Erythromycin base or Ethylsuccinate 50mg/kg/day orally divided into 4 doses daily for 14 days.

Guidelines for chlamydia and gonorrhea screening in pregnancy

- All pregnant women should be routinely tested for *Chlamydia trachomatis* at the first prenatal visit. Women aged <25 years and those at increased risk for chlamydia (i.e., women who have a new or more than one sex partner or partner with other partners) also should be retested during the third trimester.
- All pregnant women at risk for gonorrhea or living in an area in which the prevalence of *Neisseria gonorrhoeae* is high should be tested at the first prenatal visit for *N. gonorrhoeae*. State guidelines further clarify that pregnant women at risk for gonorrhea include those < 25 years of age, with a history of gonorrhea in the previous two years, with more than one sex partner in the previous 12 months or a partner with other partners. Prevalence of gonorrhea may be high among African American women over the age of 25, thus screening these women above the age of 25 may be indicated. A repeat test should be performed during the third trimester for those at continued risk.
- Pregnant women who did not receive appropriate screening as part of prenatal care should be tested for chlamydia and gonorrhea prior to delivery, and results obtained as soon as possible.

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Our Center for infectious Diseases (CID) encourages you to monitor the CDC web site for future information on the shortage of erythromycin (0.5%) ophthalmic ointment. Please feel free to contact Dr. Gail Bolan if you have any questions or have severely low supplies at gail.bolan@cdph.ca.gov or at (510) 620-3400.

Sincerely,

Original Signed by Kathleen Billingsley, R.N.

Kathleen Billingsley, R.N.
Deputy Director
Center for Health Care Quality