November 9, 2023

Subject: Erythromycin 0.5% Ophthalmic Ointment Shortage Update and Guidance

Dear Healthcare Providers,

Due to an ongoing shortage of **erythromycin 0.5% ophthalmic ointment** (erythromycin), the Texas Department of State Health Services (DSHS) is providing recommendations to assist healthcare providers experiencing strained supplies.

Erythromycin 0.5% ophthalmic ointment is the recommended regimen to prevent ophthalmia neonatorum caused by *N. gonorrhoeae.* Texas Health and Safety Code 81.091 requires providers to administer gonorrhea ocular prophylaxis of newborns in accordance with DSHS guidance (see also Texas Administrative Code 97.136).

Healthcare providers may consider the following recommendations until erythromycin supply concerns are resolved. Erythromycin continues to be the best regimen to prevent ophthalmia neonatorum.

**Recommendations for Healthcare Providers:**

- **Follow Centers for Disease Control and Prevention (CDC) guidance if supply is exhausted:** If erythromycin ointment is unavailable, infants at risk for exposure to *N. gonorrhoeae,* especially those born to a mother at risk for gonococcal infection or with no prenatal care, may be administered ceftriaxone 25–50 mg/kg body weight IV or IM, not to exceed 250 mg in a single dose.

  Other topical medications are not recommended: tetracycline ophthalmic ointment and silver nitrate are no longer available in the United States; gentamicin was associated with chemical conjunctivitis during a previous erythromycin shortage; and povidone-iodine has limited data on its risks and benefits. Additional treatment guidance is available in the CDC's STI Treatment Guidelines, 2021.

- **Communicate with patients:** Proactively communicate with patients about the shortage and provide clear guidance on the available treatment options.

- **Report shortage effects to DSHS:** Healthcare providers should report the adverse effects of the erythromycin shortage. Notify DSHS at hivstd@dshs.texas.gov of any shortage of this product so DSHS can provide situational awareness to CDC and the U.S. Food and Drug Administration (FDA).

- **Stay updated:** Stay informed about updates or changes to the erythromycin shortage through reliable sources like DSHS, FDA, CDC, local health departments, and professional healthcare associations. Regularly check for new information and promptly disseminate updates to your healthcare team.

## **Federal Efforts to Address the Shortage:**

To address the current erythromycin shortage, FDA has worked with Fera Pharmaceuticals, LLC on the temporary importation of non-FDA approved products from Canada.

- Effective immediately, and during this temporary period, Fera will distribute erythromycin, 5mg/g (NDC 48102-057-11).
- The strength and qualitative composition of the imported drug product are the same as the FDA-approved drug product.
- Both products meet the U.S. monograph specifications.
- Additional details and comparison of the FDA-approved versus Fera Canada-approved product can be found at the FDA website, Fera Dear Healthcare Provider Letter | Erythromycin (fda.gov).

Providers can work through their established procurement channels to obtain additional supply erythromycin. Providers may also contact Fera for more options at 516-277-1449.

The most current information on the shortage can be found at the FDA Drug Shortages website.

## **Resources:**

- HIV/STD Program | Texas DSHS
- FDA Drug Shortages: Erythromycin
- CDC - STD Treatment - Drug notices
- CDC's STI Treatment Guidelines, 2021

DSHS is closely monitoring the erythromycin shortage and will provide updates as they become available. Thank you for your partnership in ensuring health and well-being of all Texans. For further questions or concerns regarding the erythromycin shortage, please contact DSHS at hivstd@dshs.texas.gov.


Sincerely,

Joshua Hutchison
Associate Commissioner, Infectious Disease Prevention Division
Texas Department of State Health Services