

Lieutenant Governor

## Department of Health & Human Services

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Subject: Erythromycin 0.5% ophthalmic ointment shortage update and guidance

Dear healthcare provider,

The Utah Department of Health and Human Services (DHHS) has enacted an emergency rule due to an ongoing shortage of **erythromycin 0.5% ophthalmic ointment**. We are also providing recommendations to help healthcare providers who are unable to obtain this medication.

Erythromycin 0.5% ophthalmic ointment is the only recommended regimen to prevent ophthalmia neonatorum caused by *N. gonorrhoeae*. R386-702-14 requires providers to administer gonorrhea ocular prophylaxis to newborns. During this period of supply chain disruption, healthcare providers should follow the alternative recommendations below when they are unable to access erythromycin 0.5% ophthalmic ointment.

## **Recommendations for healthcare providers**

- Follow <u>Centers for Disease Control and Prevention</u> (CDC) guidance:
  - If erythromycin 0.5% ophthalmic ointment is unavailable, ceftriaxone 25–50 mg/kg body weight IV or IM, not to exceed 250 mg in a single dose, can be given to infants at risk for exposure to *N. gonorrhoeae*, including infants born to mothers with no prenatal care; or infants born to mothers at risk for gonococcal infection (women aged <25 years and those aged ≥25 years who have a new sex partner, more than one sex partner, a sex partner with concurrent partners, a sex partner who has an STI, or live in a community with high rates of gonorrhea).
  - Consider screening for gonorrhea at delivery for women who were not tested during pregnancy or who are at risk for infection. Make sure follow up and treatment for mother and infant is prompt. If the mother and/or infant tests positive for gonorrhea, treat according to guidelines found in: <a href="Monococcal Infections Among Neonates STI Treatment Guidelines">Gonococcal Infections Among Neonates STI Treatment Guidelines</a>.
  - The use of other topical medications is not recommended: tetracycline ophthalmic ointment, and silver nitrate are no longer available in the US; gentamicin was associated with chemical conjunctivitis during a previous erythromycin shortage; and there is limited data available on povidone-iodine risks and benefits. Additional treatment guidance is available in the CDC's STI Treatment Guidelines, 2021.

- Communicate with patients: Talk to your patients about the shortage and give them clear guidance on the available treatment options.
- **Stay updated:** Stay informed about updates or changes to the erythromycin 0.5% ophthalmic ointment shortage through reliable sources such as <u>FDA</u>, <u>CDC</u>, local health departments, and professional healthcare associations. Check for new information regularly and promptly give those updates to your healthcare team.

## Federal efforts to address the shortage

The FDA has worked with Fera Pharmaceuticals, LLC to temporarily import non-FDA approved products from Canada to address the current erythromycin 0.5% ophthalmic ointment shortage.

- 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 US monograph specifications.
- Additional details and comparison of the FDA-approved versus Fera Canada-approved product can be found at the FDA website and in a Fera Provider Letter.

Providers should work through their established procurement channels to get additional supplies of erythromycin 0.5% ophthalmic ointment. 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:**

- FDA Drug Shortages: Erythromycin
- CDC STD Treatment Drug notices
- CDC's STI Treatment Guidelines, 2021

DHHS is closely monitoring the erythromycin 0.5% ophthalmic ointment shortage and will provide updates as they become available. Thank you for your partnership in ensuring the health and well-being of all Utahns. For further questions or concerns, or if you are experiencing impacts of the erythromycin 0.5% ophthalmic ointment shortage, contact DHHS at <a href="mailto:epi@utah.gov">epi@utah.gov</a> or 801-538-6191.

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