



Erythrocin Lactobionate I.V (035492560205), Lyophilized Powder for Injection

רוקח/ת יקר/ה, רופא/ה יקר/ה

חברת ביוטיס בע"מ מבקשת להודיעכם על עדכון העלון לרופא לתכשיר אריתרוצין לקטוביאונאט תוך ורידי.

ההתוויה המאושרת לתכשיר:

For the treatment of bacterial infections susceptible to erythromycin and require I.V treatment.

התכשיר מכיל: Erythromycin 1.0 g/vial

העלון לרופא עודכן. העדכון כולל החמרות.

התוספות המודגשות ברקע צהוב מהוות החמרה. קיימים שינויים נוספים, כולל שינויי עריכה, שאינם מהווים החמרה ואינם נכללים בהודעה זו.

4.3 Contraindications

Concomitant administration of erythromycin and lomitapide is contraindicated (see section 4.5).

4.4 Special warnings and precautions for use

Carefully consider the balance of benefits and risks before prescribing erythromycin for any patients taking hydroxychloroquine or chloroquine, because of the potential for an increased risk of cardiovascular events and cardiovascular mortality (see section 4.5).

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant administration of erythromycin with lomitapide is contraindicated due the potential for markedly increased transaminases (see section 4.3).

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Corticosteroids: Caution should be exercised in concomitant use of erythromycin with systemic and inhaled corticosteroids that are primarily metabolised by CYP3A due to the potential for increased systemic exposure to corticosteroids. If concomitant use occurs, patients should be closely monitored for systemic corticosteroid undesirable effects.

Hydroxychloroquine and chloroquine: Erythromycin should be used with caution in patients receiving these medicines known to prolong the QT interval due to the potential to induce cardiac arrhythmia and serious adverse cardiovascular events.

Observational data have shown that co-administration of azithromycin with hydroxychloroquine in patients with rheumatoid arthritis is associated with an increased risk of cardiovascular events and cardiovascular mortality. Because of the potential for a similar risk with other macrolides when used in combination with hydroxychloroquine or chloroquine, careful consideration should be given to the balance of benefits and risks before prescribing erythromycin for any patients taking hydroxychloroquine or chloroquine.

4.6 Fertility, pregnancy and lactation

There is a large amount of data from observational studies performed in several countries on exposure to erythromycin during pregnancy, compared to no antibiotic use or use of another antibiotic during the same period (>24,000 first trimester exposures). While most studies do not suggest an association with adverse fetal effects such as major congenital malformations, cardiovascular malformations or miscarriage, there is limited epidemiological evidence of a small increased risk of major congenital malformations, specifically cardiovascular malformations following first trimester exposure to erythromycin.

Therefore, erythromycin should only be used during pregnancy if clinically needed and the benefit of treatment is expected to outweigh any small increased risks which may exist.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס ע"י פניה לחברת
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