



מאי 2020

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 אומץ כלשונו מהאסמכתא הבאה: Summary of Product Characteristics (SPC), כפי שאושרה באנגליה, מלבד התאמות לתנאי הרישום בארץ (בסעיפים הבאים: 1,2,3,4,6).
להלן עדכונים המהווים החמרה במידע הבטיחותי (מסומנים בצהוב):

4.3 Contraindications

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Erythromycin is contraindicated in patients taking **simvastatin, tolterodine, mizolastine, amisulpride**, astemizole, terfenadine, domperidone, cisapride or pimozide.

Erythromycin should not be given to patients with a history of QT prolongation (congenital or documented acquired QT prolongation) or ventricular cardiac arrhythmia, including torsades de pointes (see section 4.4 and 4.5).

Erythromycin should not be given to patients with electrolyte disturbances (hypokalaemia, hypomagnesaemia due to the risk of prolongation of QT interval).

4.4 Special warnings and precautions for use

Cardiovascular Events



Prolongation of the QT interval, reflecting effects on cardiac repolarisation imparting a risk of developing cardiac arrhythmia and torsades de pointes, have been seen in patients treated with macrolides including erythromycin (see sections 4.3, 4.5 and 4.8). Fatalities have been reported.

Erythromycin should be used with caution in the following;

Patients with coronary artery disease, severe cardiac insufficiency, conduction disturbances or clinically relevant bradycardia.

Patients concomitantly taking other medicinal products associated with QT prolongation (see section 4.3 and 4.5).

Elderly patients may be more susceptible to drug-associated effects on the QT interval (see section 4.8).

Epidemiological studies investigating the risk of adverse cardiovascular outcomes with macrolides have shown variable results. Some observational studies have identified a rare short term risk of arrhythmia, myocardial infarction and cardiovascular mortality associated with macrolides including erythromycin. Consideration of these findings should be balanced with treatment benefits when prescribing erythromycin.

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As with other macrolides, rare serious allergic reactions, including acute generalised exanthematous pustulosis (AGEP) have been reported. If an allergic reaction occurs, the drug should be discontinued and appropriate therapy should be instituted. Physicians should be aware that reappearance of the allergic symptoms may occur when symptomatic therapy is discontinued.

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There have been reports of infantile hypertrophic pyloric stenosis (IHPS) occurring in infants following erythromycin therapy. Epidemiological studies including data from meta-analyses suggest a 2-3-fold increase in the risk of IHPS following exposure to erythromycin in infancy. This risk is highest following exposure to erythromycin during the first 14 days of life. Available data suggests a risk of 2.6% (95% CI: 1.5 -4.2%) following exposure to erythromycin during this time period. The risk of IHPS in the general population is 0.1-0.2%.

4.5 Interaction with other medicinal products and other forms of interaction

Increases in serum concentrations of the following drugs metabolised by the cytochrome P450 system may occur : when administered concurrently with erythromycin: acenocoumarol, alfentanil, astemizole, bromocriptine, carbamazepine, cilostazol, cyclosporin, digoxin, dihydroergotamine, disopyramide, ergotamine, hexobarbitone, methylprednisolone, midazolam, omeprazole, phenytoin, quinidine, rifabutin, sildenafil, tacrolimus, terfenadine, domperidone,....



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Oral anticoagulants: there have been reports of increased anticoagulant effects when erythromycin and oral anticoagulants (e.g. warfarin, rivaroxaban) are used concomitantly.

4.6 Pregnancy and lactation

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There have been reports that maternal macrolide antibiotics exposure within 7 weeks of delivery may be associated with a higher risk of infantile hypertrophic pyloric stenosis (IHPS).

Erythromycin can be excreted into breast-milk. Caution should be exercised when administering erythromycin to lactating mothers due reports of infantile hypertrophic pyloric stenosis in breast-fed infants.

4.8 Undesirable effects

Cardiac disorders:

QTc interval prolongation, torsades de pointes, palpitations, and cardiac rhythm disorders including ventricular tachyarrhythmias, Cardiac arrest, ventricular fibrillation (frequency not known).

Eye disorders:

Mitochondrial Optic Neuropathy

Not known: acute generalised exanthematous pustulosis (AGEP)

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס ע"י פניה לחברת ביוטיס, רח' המלאכה 22 ראש-העין, טל: 03-9002008

בברכה,

מג'ר נעמי שאקו עזרא

הרוקחת הממונה