

# הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך אישור העלון: 12.16

שם תכשיר באנגלית ומספר הרישום Cubicin Reg.No:131 21 30994 01

שם בעל הרישום Merck Sharp & Dohme Israel Ltd.

טופס זה מיועד לפרוט החמרות בלבד !

## ההחמרות המבוקשות

טקסט חדש	טקסט נוכחי	פרק בעלון
<p>The following adverse reactions have been identified during postapproval use of CUBICIN. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency reliably or establish a causal relationship to drug exposure.</p> <p><b>Blood and lymphatic system disorders: anemia</b>  <b>General and administration site conditions: pyrexia</b></p> <p>Immune System Disorders: anaphylaxis; hypersensitivity reactions, including angioedema, drug rash with eosinophilia and systemic symptoms (DRESS), pruritus, hives, shortness of breath, difficulty swallowing, truncal erythema, and pulmonary eosinophilia [see Contraindications (4), Warnings and Precautions (5.1)]</p> <p>Infections and Infestations: Clostridium difficile-associated diarrhea [see Warnings and Precautions (5.6)]</p> <p>Musculoskeletal Disorders: myoglobin increased; rhabdomyolysis (some reports involved patients treated concurrently with CUBICIN and HMG-CoA reductase inhibitors) [see Warnings and Precautions (5.2), Drug Interactions (7.1), and Clinical Pharmacology (12.3)]</p> <p>Respiratory, Thoracic, and Mediastinal Disorders: cough, eosinophilic pneumonia [see Warnings and Precautions (5.3)]</p> <p>Nervous System Disorders: peripheral neuropathy [see Warnings and Precautions (5.4)]</p> <p>Skin and Subcutaneous Tissue Disorders: serious skin reactions, including Stevens-Johnson syndrome and vesiculobullous rash (with or without mucous membrane involvement), <b>acute generalized exanthematous pustulosis.</b></p> <p>Gastrointestinal Disorders: nausea, vomiting</p> <p><b>Renal and urinary disorders: acute kidney injury, renal insufficiency, and renal failure</b></p> <p><b>Special Senses: visual disturbances</b></p>	<p>The following adverse reactions have been identified during postapproval use of CUBICIN. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency reliably or establish a causal relationship to drug exposure.</p> <p><i>Immune System Disorders: anaphylaxis; hypersensitivity reactions, including angioedema, drug rash with eosinophilia and systemic symptoms (DRESS), pruritus, hives, shortness of breath, difficulty swallowing, truncal erythema, and pulmonary eosinophilia [see Contraindications (4), Warnings and Precautions (5.1)]</i></p> <p><i>Infections and Infestations: Clostridium difficile-associated diarrhea [see Warnings and Precautions (5.6)]</i></p> <p><i>Musculoskeletal Disorders: myoglobin increased; rhabdomyolysis (some reports involved patients treated concurrently with CUBICIN and HMG-CoA reductase inhibitors) [see Warnings and Precautions (5.2), Drug Interactions (7.1), and Clinical Pharmacology (12.3)]</i></p> <p><i>Respiratory, Thoracic, and Mediastinal Disorders: cough, eosinophilic pneumonia [see Warnings and Precautions (5.3)]</i></p> <p><i>Nervous System Disorders: peripheral neuropathy [see Warnings and Precautions (5.4)]</i></p> <p><i>Skin and Subcutaneous Tissue Disorders: serious skin reactions, including Stevens-Johnson syndrome and vesiculobullous rash (with or without mucous membrane involvement)</i></p> <p>Gastrointestinal Disorders: nausea, vomiting</p>	<p>6.2 Post –Marketing Experience</p>