澳門特別行政區政府
Governo da Região Administrativa Especial de Macau
衛　生　局
Serviços de Saúde

參照編號 0849/DAF/10　　日期: 03/08/2010
Nº ref.　　Data/Date:

由
De/From:　部門/Dept.: 藥物事務廳 Department of Pharmaceutical Affairs
簽署者/Ass./Signat.: 蔡炳祥廳長 Dr. Choi Peng Cheong – Department Chief
傳真機/Fax: (853)-28524016

致: 醫生、藥劑師及其他衛生專業人士
Para/To: Physicians, pharmacists and other healthcare professionals

主題: 關於daptomycin(Cubicin®)安全性的最新資訊
Ass./Subject: Latest safety update on daptomycin(Cubicin®)

頁數: 1/3
Nº folhas/N.pages:

隨件附上一則關於daptomycin(Cubicin®)安全性的最新資訊, 請醫生、藥劑師及其他衛生專業人士參閱, 如台端懷疑由上述或其他藥物引致的任何不良反應, 請以下列任一方式向本廳通報：

- 網上通報 - http://www.ssm.gov.mo/design/webservices/c_wservices_main.htm
- 郵寄 - 澳門士多烏拜斯大馬路 51號 華仁中心二樓
- 傳真 – 28524016

通報人士可親臨藥物事務廳索取或在http://www.ssm.gov.mo/design/services/serpt_chn.pdf網址上下載通報表格。如有任何疑問, 請於辦公時間致電85983517或85983439與藥物監測暨管理處楊燕雯藥劑師或林俊耀藥劑師聯絡, 倘遇緊急的情況, 亦可於非辦公時間傳呼85008068。

謹祝　台安!

Attached herewith is the latest safety update on daptomycin (Cubicin®) for your reference. If physicians, pharmacists or other healthcare professionals suspect any kind of adverse reaction subsequent to the use of the above or any other medication, please report through any of the following methods：

- Online - http://www.ssm.gov.mo/design/webservices/c_wservices_main.htm
- Mail to - 51 Avenida do Sidonio Pais, Edificio China Plaza, 2nd Floor, Macao S.A.R., China
- Fax to - 853-28524016

The report form can be collected in person at Department of Pharmaceutical Affairs or downloaded from the website designated as http://www.ssm.gov.mo/design/services/serpt_chn.pdf. Should you have any query, please contact Ms. Beatrice Young or Mr. Jeffrey Lam at 8598-3517 or 8598-3439 respectively from the Division of Pharmacovigilance and Pharmacoeconomics during office hours. In case of urgent situations during off hours, please page 85008068.

Thanking you in advance for your attention!

藥物事務廳廳長
Chief, Department of Pharmaceutical Affairs

蔡炳祥
Choi Peng Cheong

澳門特別行政區政府
Governo da Região Administrativa Especial de Macau
衛　生　局
Serviços de Saúde

主題：　關於daptomycin(Cubicin®)安全性的最新資訊
Subject：Latest safety update on daptomycin (Cubicin®)

Daptomycin (Cubicin®)爲治療嚴重皮膚感染和血液感染的靜脈注射用抗菌藥，早於2007年，美國食物及藥物管理局(USFDA)已把肺部嗜酸性粒細胞增多(pulmonary eosinophilia)列爲daptomycin (Cubicin®)上市後發現的其中一項不良反應，並將其加入該藥的說明書中。自此，該局回顧了與Cubicin®有關的嗜酸性粒細胞性肺炎的已發表個案，並於其資料庫中確認了從2004至2010期間，共有7宗相關個案。嗜酸性粒細胞性肺炎是一種罕見且嚴重的病症，病人的肺部浸潤了嗜酸性粒細胞。嗜酸性粒細胞性肺炎的症狀包括發熱、咳嗽、呼吸短促和呼吸困難。有鑑於此，USFDA對醫生及其他衛生專業人士作出下列關於daptomycin (Cubicin®)的建議：

- 應緊密監測使用daptomycin的病人有否出現嗜酸性粒細胞性肺炎。
- 於開始治療前，與病人討論有關使用daptomycin的臨床效益及潛在的風險，包括發生嗜酸性粒細胞性肺炎的風險。
- 觀察病人是否出現嗜酸性粒細胞性肺炎的症狀，包括新發生或惡化的發熱情況、窒息、呼吸困難，以及在胸部造影時發現新的浸潤。
- 當發現病人出現嗜酸性粒細胞性肺炎的症狀時，須停用daptomycin，並根據病人的臨床狀況進行治療。

藥物監測暨管理處

Back in 2007 the United States Food and Drug Administration (USFDA) added pulmonary eosinophilia as one of the post-marketing adverse reactions to the product information of daptomycin (Cubicin®), an intravenous antibacterial to treat serious skin infections and bloodstream infections. Since then, the Agency has reviewed published case reports of Cubicin®-associated eosinophilic pneumonia and identified 7 cases of eosinophilic pneumonia between 2004 and 2010 from her reporting database. Eosinophilic pneumonia is a rare, but serious condition where the patients' lungs were filled with eosinophils. Symptoms of eosinophilic pneumonia include fever, cough, shortness of breath, and difficulty breathing. In view of this, USFDA would like to inform all physicians and healthcare professionals about the following advice on daptomycin (Cubicin®):

- closely monitor patients being treated with daptomycin for eosinophilic pneumonia.
- discuss with patients about the clinical benefits and potential risks of daptomycin including the risk of eosinophilic pneumonia, prior to beginning treatment.
- monitor patients for signs and symptoms of eosinophilic pneumonia, including new onset or worsening fever, dyspnea, difficulty breathing, and new infiltrates on chest imaging studies.
- discontinue daptomycin in patents exhibiting signs and symptoms of eosinophilic pneumonia and treat him/her as clinically indicated.

Division of Pharmacovigilance
and Pharmacoeconomics(DFF)

參考資料/Reference and website：
http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm220273.htm