



澳門特別行政區政府
Governo da Região Administrativa Especial de Macau
衛生局
Serviços de Saúde

No.1

參照編號 0984/DAF/10

日期: 26/08/2010

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: 關於含tocilizumab (Actemra®)安全性的最新資訊

Ass./Subject: Latest safety update on tocilizumab (Actemra®)

頁數: 1/2

Nº folhas/N.pages:

隨件附上一則關於tocilizumab (Actemra®)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 tocilizumab (Actemra®) 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tocilizumab (Actemra[®])安全性的最新資訊
Subject：Latest safety update on tocilizumab (Actemra[®])

香港衛生署公佈，接獲一宗海外因使用tocilizumab (Actemra[®]) 靜脈注射液後產生過敏反應致死的個案。該藥主要與甲氨蝶呤併用，以治療中度至重度類風濕關節炎。一名67歲女病人，在接受第5劑的tocilizumab注射液後引發過敏致死事故。此例是使用此藥後產生過敏反應致死的首宗個案。臨床試驗數據顯示，在所有服用tocilizumab的病人中，因使用該藥而引發顯著的臨床過敏反應並需停藥的個案約有0.3%。基於此，現通知醫生、藥劑師及其他衛生專業人士注意以下事項：

- 當處方、發放以及輸注該藥給予病人時需額外留心。
- 如病人產生過敏或其他嚴重過敏反應，應立即停藥，以適當的療法處理，以及永不使用tocilizumab。

藥物監測暨管理處

The Hong Kong Department of Health announced about an overseas case of fatal anaphylaxis after the administration of tocilizumab (Actemra[®]), an intravenous medication mainly used in combination with methotrexate for the treatment of moderate and severe active rheumatoid arthritis. A 67-year old woman died of the anaphylactic event after the fifth infusion of tocilizumab. This is the first reported case of fatal anaphylaxis on a patient treated with this drug. Clinically significant hypersensitivity reactions associated with tocilizumab and requiring treatment discontinuation have been reported in 0.3% of all patients receiving tocilizumab in clinical trials. In view of this, the following advice is recommended to the prescribers and other healthcare professionals :

- exercise extra caution when prescribing, supplying and administering this drug to their patients.
- discontinue the administration promptly should an anaphylactic or other serious hypersensitivity reaction occurs, initiate appropriate medical management and discontinue tocilizumab permanently.

Division of Pharmacovigilance
and Pharmacoeconomics (DFF)

參考資料/Reference and website :

http://www.psdh.gov.hk/eps/webpage_c.jsp?simplifiedChinese=N