



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

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De/From: 部門/Dept.: 藥物事務廳 Department of Pharmaceutical Affairs

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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: 關於紅血球生成素(erythropoiesis-stimulating agents, ESAs)安全性的最新資訊

Ass./Subject: Latest safety update on erythropoiesis-stimulating agents (ESAs)

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Nº folhas/N. pages:

隨件附上一則關於紅血球生成素(erythropoiesis-stimulating agents, ESAs)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_ws services_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 erythropoiesis-stimulating agents (ESAs). 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_ws services_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



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繼藥物監測暨管理處於去年發出關於紅血球生成素(erythropoiesis-stimulating agents, ESAs)安全性的資訊後，最新的數據顯示，ESAs在慢性腎病病人中出現心血管不良事件的風險較高，因此，爲了確保使用ESAs的安全性，美國食物及藥物管理局(USFDA)進一步作出謹慎使用這類藥物的建議，包括限制慢性腎病病人的劑量。本處也謹此提醒醫生、藥劑師及其他衛生專業人士：

- 使用ESAs時，設定血紅蛋白水平高於11g/dL並不會給予病人額外的效益，卻會增加嚴重心血管不良事件的風險；
- 目前的臨床試驗並未確認血紅蛋白處於哪種水平或使用何種ESA劑量或給藥方案時，心血管不良事件的風險才不會增加；
- 應對病人按個體化調整治療方案，令減少輸血的同時，可給予最低的ESA劑量；
- 對於不需透析的慢性腎病病人：
 - a. 只有當血紅蛋白水平低於10g/dL時，才考慮開始ESA治療。若病人的血紅蛋白反而下降表示需要輸注紅血球，此時需防止紅血球引起的同種免疫反應及其他與輸血相關的風險；
 - b. 如血紅蛋白水平高於10g/dL時，需減少ESA的劑量或間斷給藥，並使用足以減少輸血需要的最低ESA劑量。
- 對於需要透析的慢性腎病病人：
 - a. 於血紅蛋白水平低於10g/dL時，開始ESA治療；
 - b. 如血紅蛋白水平接近或高於11g/dL時，減少ESA的劑量或間斷給藥。
- 開始或調整治療時，最少每周監測病人紅血蛋白的水平，待該水平穩定後，最少每月監測一次。
- 如病人在12周的ESA劑量遞增周期內療效仍不理想，繼續增加劑量並不會提高效益，且可能增加相應的風險。

藥物監測暨管理處

Following to our safety alert on erythropoiesis-stimulating agents (ESAs) last year, latest data showing increased risks of cardiovascular events with ESAs in patients with chronic kidney disease (CKD), therefore, United Food and Drug Administration (USFDA) modified recommendations for more conservative dosing of erythropoiesis-stimulating agents (ESAs) in this patient population to improve the safe use of these drugs. Division of Pharmacovigilance and Pharmacoeconomics also recommends physicians, pharmacists and other health professionals:

- using ESAs to target a hemoglobin level of greater than 11 g/dL increases the risk of serious adverse cardiovascular events and has not been shown to provide additional patient benefit;
- no clinical trial has identified a hemoglobin target level, ESA dose, or dosing strategy that does not increase these risks;
- therapy should be individualized to the patient and the lowest possible ESA dose given to reduce the need for transfusions;
- for patients with CKD not on dialysis:
 - a. consider initiating ESA treatment only when the hemoglobin level is less than 10 g/dL. The rate of hemoglobin decline indicates the likelihood of requiring a red blood cell transfusion. Reducing the risk of alloimmunization and other red blood cell transfusion-related risks is a goal;
 - b. if the hemoglobin level exceeds 10 g/dL, reduce or interrupt the dose of ESA and use the lowest dose of ESA sufficient to reduce the need for red blood cell transfusions.



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- for patients with CKD on dialysis:
 - a. initiate ESA treatment when the hemoglobin level is less than 10 g/dL;
 - b. if the hemoglobin level approaches or exceeds 11 g/dL, reduce or interrupt the dose of ESA.
- when initiating or adjusting therapy, monitor hemoglobin levels at least weekly until stable, then monitor at least monthly;
- for patients who do not respond adequately over a 12-week escalation period, increasing the ESA dose further is unlikely to improve response and may increase risks.

Division of Pharmacovigilance
and Pharmacoeconomics(DFF)

參考資料/Reference and website :
<http://www.fda.gov/Drugs/DrugSafety/ucm259639.htm>