



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 0552/DAF/11

日期: 13/05/2011

Nº ref.

Data/Date:

由

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prasugrel (Efient®)和lenalidomide (Revlimid®)安全性的最新資訊

Ass./Subject: Latest safety updates on prasugrel (Efient®) and lenalidomide (Revlimid®)

頁數: 1/3

Nº folhas/N.pages:

隨件附上兩則關於prasugrel (Efient®)和lenalidomide (Revlimid®)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_wservlets_main.htm
- 郵寄 - 澳門士多利拜斯大馬路 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, 亦可於非辦公時間致電63009255。

謹祝 台安!

Attached herewith are two latest safety updates on prasugrel (Efient®) and lenalidomide (Revlimid®). 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_wservlets_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 call 63009255.

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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主題：關於prasugrel (Efient[®])和lenalidomide (Revlimid[®])安全性的最新資訊
Subject：Latest safety updates on prasugrel (Efient[®]) and lenalidomide (Revlimid[®])

Prasugrel (Efient[®])與嚴重過敏反應

Daiichi-Sankyo公司和Eli Lilly公司通知衛生專業人士關於prasugrel (Efient[®])安全性的最新資訊，該藥是結構為thienopyridine的抗血小板新藥，以單獨使用或併用aspirin來預防血栓性血管疾病。上市後不良反應的報告指出，使用Efient[®]可出現罕見的嚴重過敏反應，包括血管神經性水腫，然而，過敏反應的發生時間並未確定，可於治療後即時出現，或經過數小時，甚至5至10天才出現。部分對Efient[®]產生過敏反應的病人同時具有對clopidogrel過敏的病史，而一些未曾使用過clopidogrel的病人也可能對Efient[®]產生過敏反應。因此，當使用Efient[®]時，藥物監測暨管理處提醒醫生、藥劑師及其他衛生專業人士：

1. 於處方、調配或使用Efient[®]時，醫生和藥劑師應知會病人該藥具有出現過敏反應的潛在風險。
2. 對於服用thienopyridine類藥物(如clopidogrel和ticlopidine)後曾出現過敏反應的病人，醫生和藥劑師應特別注意病人使用Efient[®]後出現過敏反應的潛在風險，包括血管神經性水腫。
3. 教導病人如出現懷疑為過敏反應的症狀時，應立即通知醫生。

Lenalidomide (Revlimid[®])與第二原發性惡性腫瘤增加的潛在風險

英國藥物管理局(MHRA)和Celgene公司通知衛生專業人士關於lenalidomide (Revlimid[®])安全性的最新資訊，該藥是具有抗血管增生和抗紅血球生成作用的抗腫瘤藥物，併用dexamethasone以治療曾接受過最少一種療法的多發性骨髓瘤病人。上市後數據顯示，接受用於非核准適應症的臨床試驗病人，出現第二原發性惡性腫瘤(新的癌症)的機會較高。MHRA正等待歐盟人用藥物委員會(CHMP)對Revlimid[®]適應症的回顧性研究，對於Revlimid[®]所核准的適應症，MHRA目前並未延緩、改變或限制病人使用，但並不建議用於所有非核准的適應症。

基於上述原因，藥物監測暨管理處建議衛生專業人士，除非經仔細評估後認為使用Revlimid[®]的效益高於出現第二原發性惡性腫瘤的風險，否則不應使用該藥於非核准的適應症。

藥物監測暨管理處

Prasugrel (Efient[®]) and serious hypersensitivity

Daiichi-Sankyo and Eli Lilly and Company would like to notify all healthcare professionals about the latest safety update about prasugrel (Efient[®]), a new anti-platelet thienopyridine drug used alone or co-administered with aspirin for the prevention of thromboembolic disorders. Postmarketing adverse reports described the occurrence of rare and serious hypersensitivity reactions including angioedema in patients exposed to Efient[®], however, times to onset for the appearance of hypersensitive reactions did vary, which ranged from immediately after treatment, or over the following few hours, or even up to 5-10 days. Some of these reports where patients developed hypersensitivity to Efient[®] coincided with those patients who had history of hypersensitivity reactions to clopidogrel, while in some other patients, who had no previous exposure to clopidogrel, did also experience hypersensitivity reactions. Hence, we would like to advise physicians, pharmacists and other healthcare professionals to be aware of the following recommendations

— on the use of Efient[®] :



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1. upon prescribing, dispensing or administering Efient[®], it is important for prescribers to inform patients and for pharmacist to counsel patients about the potential risk of hypersensitivity reactions.
2. prescribing physician and dispensing pharmacist should particularly be aware of the potential risk of hypersensitivity reactions, including angioedema in patients with a previous known history of hypersensitivity reactions to thienopyridines (eg. clopidogrel and ticlopidine).
3. educate your patients to notify their physicians immediately if they experience symptoms suggestive of hypersensitivity.

Lenalidomide (Revlimid[®]) and increased potential risk of developing second primary malignancies

The Medicines and Health Products Regulatory Agency (MHRA) and Celgene, Europe would like to inform all healthcare professionals about the latest clinical update on lenalidomide (Revlimid[®]), an antineoplastic with antiangiogenic and antierythropoietic properties, is authorized for use in combination with dexamethasone for multiple myeloma patients who have received at least one previous treatment. Postmarketing data reviews a higher incidence of second primary malignancies (new cancer) in patients treated with Revlimid[®] has been observed in clinical studies conducted outside the authorized indication. While pending for the results of the Committee for Medicinal Products for Human Use (CHMP)'s reviews on the authorized use of Revlimid[®] as stated above, MHRA is neither recommending to delay, modify, restrict the use of Revlimid[®] in patients under current approval, nor to agree to any of its unlicensed uses. In light of the above observation we do not advise healthcare professionals to use Revlimid[®] off-label or beyond its licensed use unless thorough consideration has been exercised indicating that benefits of using Revlimid[®] outweigh the developing risks of second primary malignancies.

Division of Pharmacovigilance
and Pharmacoeconomics(DFF)

參考資料/References and websites :

http://fdaapprovalsreview.com/Prasugrel_Effient_.html

<http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON108684>