



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 1452/DAF/10
Nº ref.

日期: 23/12/2010
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bevacizumab(Avastin®)處方指引的最新資訊

Ass./Subject: Latest guidelines on bevacizumab(Avastin®)

頁數: 1/3

Nº folhas/N.pages:

隨件附上一則關於bevacizumab(Avastin®)處方指引的最新資訊, 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 guidelines on bevacizumab(Avastin®). 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bevacizumab(Avastin[®])處方指引的最新資訊
Subject： Latest guidelines on bevacizumab(Avastin[®])

Bevacizumab(Avastin[®])為一用於治療多種癌症的抗腫瘤藥物，美國食物及藥物管理局(USFDA)與歐盟藥物管理局(EMA)近期發出了關於Avastin[®]用於乳癌的處方指引：

- USFDA建議取消Avastin[®]用於治療乳癌病人的適應症

USFDA於評估數個有關Avastin[®]治療乳癌病人的研究後，認為該藥不會延長病人的生存期或減慢其惡化，而且病人會出現明顯的嚴重不良反應，當中包括嚴重高血壓、出血、鼻、胃部或腸道穿孔、心臟病發和心力衰竭等。根據目前有關使用Avastin[®]治療轉移性乳癌的資料，USFDA認為使用該藥的風險高於其效益。對於正在使用Avastin[®]治療轉移性乳癌病人的腫瘤科醫生，應根據具體臨床情況，以決定病人應否繼續使用該藥治療，或改用其他適合的治療方案。

- EMA確認併用Avastin[®]和paclitaxol治療乳癌病人的好處大於風險

EMA指現在數據顯示，Avastin[®]併用paclitaxol治療轉移性乳癌病人，可延長病人的存活期和提高了生存率，因此確認其效益高於風險，並肯定其治療價值。然而，EMA並不建議Avastin[®]與docetaxel/capecitabine併用。EMA建議腫瘤科醫生：

- 對於治療效果良好的乳癌病人，應繼續併用Avastin[®]和paclitaxel作為治療方案；
- 停止併用Avastin[®]與docetaxel/capecitabine治療轉移性乳癌病人。

綜合上述，藥物監測暨管理處建議腫瘤科醫生在使用Avastin[®]治療轉移性乳癌病人時，應評估每個病人的風險-效益情況，並作出適當決定。

藥物監測暨管理處

Bevacizumab(Avastin[®]) is an anticancer medicine. Latest guidelines from United States Food and Drug Administration (USFDA) and European Medicines Agency (EMA) indicated new advices on patients with breast cancer :

- USFDA recommends removing the breast cancer indication for Avastin[®] :

After reviewing several studys about breast cancer patients using Avastin[®], USFDA determined that Avastin[®] neither prolong patients' overall survival nor slow down their disease progression. Moreover, patients experienced an increase in toxicity, which were reflected as a significant increase in side effects namely severe high blood pressure, bleeding and hemorrhage, development of nasal, gastro or intestinal perforations, heart attack or heart failure. On the basis of all available data relating to the use of Avastin[®] to treat metastatic breast cancer, the agency has determined that the risks of the drug outweigh the benefits for this use. Oncologists currently treating patients with Avastin[®] for metastatic breast cancer should use their medical judgment when deciding whether a patient should continue treatment with the drug or consider other therapeutic options.



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

- EMA confirmed concomitant use of Avastin[®] and paclitaxol
Available data indicated Avastin[®] with paclitaxol in patients with metastasized breast cancer clearly prolonged survival free of disease progression and overall survival without prejudice. This combination, therefore, continues to be a valid therapeutic option as the benefit exceeded the risk. EMA negated the concurrent uses of bevacizumab with docetaxel/capecitabine. Advice for the physicians:
 - continue using Avastin[®] and paclitaxel as a combination treatment of metastatic breast cancer and maintain current treatment modalities on patients who are responding well;
 - discontinue therapies combining Avastin[®] with docetaxel/capecitabine for patients with metastatic breast cancer.

In view light of above, Division of Pharmacovigilance and Pharmacoeconomics recommends that oncologists treating patients with metastatic breast cancer evaluate individuals of risk and benefit to decide whether to use Avastin[®].

Division of Pharmacovigilance
and Pharmacoeconomics(DFE)

參考資料/References and websites :

[http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsand Providers/UCM237171.pdf](http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM237171.pdf)

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2010/12/news_detail_001166.jsp&murl=menus/news_and_events/news_and_events.jsp&mid=WC0b01ac058004d5c1