



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 0134/DAF/11  
Nº ref.

日期: 28/01/2011  
Data/Date:

由

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

簽署者/Ass./Signat.: 吳國良代廳長 Ng Kuok Leong - Acting Chief of DAF

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ketoprofen外用製劑安全性的最新資訊

Ass./Subject: Latest safety update on topical ketoprofen

頁數: 1/2

Nº folhas/N.pages:

隨件附上一則關於ketoprofen外用製劑安全性的最新資訊, 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](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](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 a safety update on topical ketoprofen. 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](http://www.ssm.gov.mo/design/webservices/c_wservices_main.htm)
- Mail to - 51 Avenida do Sidonio Pais, Edificio China Plaza, 2<sup>nd</sup> 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](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!

藥物事務廳代廳長  
Acting Chief, Department of Pharmaceutical Affairs

Ng Kuok Leong



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ketoprofen外用製劑安全性的最新資訊  
Subject : Latest safety update on topical ketoprofen

Ketoprofen是一非甾體抗炎藥(NSAID), 可供外用以緩解由輕微創傷、肌腱炎、小關節骨關節炎、靜脈炎和腰部疾病引起的急性、局部疼痛或炎症, 歐盟藥物管理局(EMA)對於局部使用ketoprofen的外用製劑可能引起皮膚光過敏反應作出風險評估, 並指出該藥引起嚴重光過敏反應的機率非常小, 而且可通過適當措施減低該風險。雖然使用ketoprofen的外用製劑的效益仍高於其風險, EMA仍建議醫生、藥劑師及其他衛生專業人士:

- 須注意ketoprofen外用製劑具有引起光過敏反應的風險;
- 告知病人如何適當地使用ketoprofen的外用製劑;
- 確保病人知悉下列資訊:
  - i) 確保於整個治療期間及治療結束後兩星期, 接受治療的部位不會受到太陽光照射;
  - ii) 於每次使用ketoprofen後, 仔細地清潔雙手;
  - iii) 如使用藥物後出現任何皮膚反應, 應立即停止治療, 並向醫生求診。

藥物監測暨管理處

The European Medicines Agency(EMA) notified healthcare professionals about her concluded announcement over the adverse risks of skin photosensitivity reactions associated with local uses of topical ketoprofen, an non-steroidal anti-inflammatory drug(NSAID) indicated to relief acute, localized, pain or inflammation due to minor traumas, tendonitis, small-joint osteoarthritis, phlebitis and at the lower-back. Accordingly, EMA described that the risk of serious photoallergic reaction was very low and that this risk could be minimized by harmonized risk-minimization measures. Despite of the benefit of using topical ketoprofen still outweigh the above risks, EMA recommended the following to physicians, pharmacists and other healthcare professionals:

- be aware of the risk of photoallergy with topical ketoprofen;
- tell their patients how to use topical ketoprofen appropriately;
- ensure that their patients are aware of the following instruction:
  - i) make sure that the treated areas are protected from sunlight during the whole period of ketoprofen treatment and the two weeks after stopping the treatment;
  - ii) wash their hands carefully after each application of ketoprofen;
  - iii) discontinue treatment immediately if they develop any skin reaction after application of these medicines, and seek their doctor's advice.

Division of Pharmacovigilance  
and Pharmacoeconomics(DFF)

參考資料/Reference and website :

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Ketoprofen\\_topical/human\\_referral\\_000238.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580024e99&jsenabled=true](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Ketoprofen_topical/human_referral_000238.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580024e99&jsenabled=true)