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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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由

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

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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topiramate安全性的最新資訊

Ass./Subject: Latest safety update on topiramate

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隨件附上一則關於topiramate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 a latest safety update on topiramate. 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!

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


吳國良

Ng Kuok Leong



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來自North American Antiepileptic Drug Pregnancy Registry(NAAED) 和UK Epilepsy and Pregnancy Register(UKEPR)的數據同時指出，當topiramate作為抗癲癇藥單獨應用於懷孕首三個月的婦女時，對人類胎兒具有確定的風險，包括唇裂和腭裂(統稱為口裂)等出生缺陷。基於上述結果，美國食物及藥物管理局(USFDA)決定將topiramate的懷孕分級由C改為D。藥物的懷孕分級D表示臨床數據顯示藥物對人類胎兒有風險，然而，在某些情況下，孕婦使用該藥的效益可能高於其潛在風險。因此，現建議醫生、藥劑師及其他衛生專業人士：

- 對育齡婦女處方topiramate時，特別對不會造成永久損傷或死亡的適應症，須衡量其效益及風險；
- 考慮處方其他引起口裂風險較低的藥物，同時注意可能出現的其他不良反應；
- 告知育齡婦女，若在懷孕首三個月服用topiramate，嬰兒出現口裂的風險會增加；
- 對於獲處方topiramate但不準備懷孕的婦女，建議使用有效的避孕藥物，須注意當併用含有雌激素的避孕藥和topiramate時，避孕藥的效用可能會減低；
- 胎兒口裂一般發生於懷孕首三個月，在該段期間許多婦女還不知道自己已懷孕，因此，衛生專業人士必須：
 1. 建議和鼓勵病人與醫生討論使用topiramate 或其他治療方案的效益及風險；
 2. 如選擇topiramate作為治療方案：
 - i) 告知病人如在服用topiramate 期間懷孕，嬰兒出現口裂的風險會增加；
 - ii) 教導病人於開始topiramate治療後，如發現已懷孕或準備懷孕，須告知主診醫生，以便主診醫生能夠決定隨後的治療方案，或決定病人是否於懷孕期間繼續服用topiramate；
 - iii) 確保病人清楚了解，即使她們已懷孕，也不能在沒有醫生的指示下突然停止服用topiramate，若病人突然停止服用topiramate可能會造成嚴重的後果，於懷孕期間不治療癲癇可對孕婦和胎兒造成危害；
 - iv) 教導病人topiramate會分泌至乳汁中，但目前仍不清楚這對嬰兒的影響，因此，若病人接受topiramate治療，須與衛生專業人士討論最合適的餵養嬰兒方法。

藥物監測暨管理處

Data from the North American Antiepileptic Drug Pregnancy Registry(NAAED) and the UK Epilepsy and Pregnancy Register(UKEPR) indicated similar observation and positive evidence of human fetal risk, including birth defects of cleft lip and cleft palate(collectively called oral cleft), when topiramate is given as an antiepileptic monotherapy in women at their first trimester of pregnancy. In view of the above results, the United States Food and Drug Administration(USFDA) decided to relocate the pregnancy category of topiramate from C to D. Pregnancy Category D means there is positive evidence of human fetal risk based on human data but the potential benefits from use of the drug in pregnant women may be acceptable in certain situations despite its risks. Hence, we would like to communicate the following advice for physicians, pharmacists and other healthcare professionals:



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- weigh the benefits and risks of topiramate when prescribing this drug to women of childbearing age, particularly when treating a condition not usually associated with permanent injury or death;
- bear in mind about alternative medications that have a lower risk of oral clefts and other adverse birth outcomes;
- inform women of childbearing age of the increased risk for oral clefts when topiramate is used in the first trimester of pregnancy;
- recommend the use of effective contraception for women who are not planning a pregnancy when prescribed topiramate, keeping in mind the potential for a possible decrease in contraceptive efficacy when using estrogen-containing birth control with topiramate;
- recognize that fetal oral clefts occur early in the first three months of pregnancy, a period which many women may not recognize that they are pregnant, hence, it is essential for healthcare professionals to act accordingly :
 1. advise and encourage patients to openly discuss with their physician about the benefit and risk of treatment with topiramate or with other treatment options;
 2. If topiramate is the treatment being selected:
 - i) inform patients about the increased risk of having a baby with an oral cleft if they become pregnant;
 - ii) instruct them that once they initiate with topiramate therapy, they should tell their prescribing physician if they are pregnant, or are planning to or become pregnant while taking topiramate so that the attending physician can decide what is the next step of treatment for them or if they shall continue taking topiramate while they are pregnant;
 - iii) ensure the patients understand that topiramate should not be stopped abruptly without talking to their physicians even in they know that they are pregnant. Stopping topiramate suddenly can cause serious problems. Not treating epilepsy during pregnancy can be harmful to them as well as to their developing babies;
 - iv) educate patients about the fact that topiramate will pass into breast milk but nothing was known about its effect on babies, hence, patients will need talk to their healthcare professional about the best way to feed their babies if they are on topiramate.

Division of Pharmacovigilance
and Pharmacoeconomics(DFF)

參考資料/Reference and website :

<http://www.fda.gov/Drugs/DrugSafety/ucm245164.htm>
<http://www.fda.gov/Drugs/DrugSafety/ucm245011.htm>
<http://www.fda.gov/Drugs/DrugSafety/ucm245085.htm>