



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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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: 抗精神病藥物安全性的最新資訊

Ass./Subject: Latest safety update on antipsychotics

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Nº folhas/N.pages:

隨件附上一則關於抗精神病藥物安全性的最新資訊, 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 latest safety update on antipsychotics. 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 廳長  
Chief, Department of Pharmaceutical Affairs

蔡炳祥  
Choi Peng Cheong



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主題： 關於抗精神病藥物安全性的最新資訊  
Subject : Latest safety update on antipsychotics

美國食物及藥物管理局(USFDA)對孕婦於懷孕第三期服用抗精神病藥物出現的不良反應報告進行了截至2008年10月的上市後回顧研究, 結果發現68名新生兒出現錐體外症狀或戒斷症狀, 包括激動、張力過高、肌無力、震顫、嗜睡、呼吸抑制和飼養障礙。當中部分新生兒的錐體外症狀和戒斷症狀在不需處理的情況下於數小時或數天內消失, 然而部分新生兒需要住院治療, 甚至延長住院時間。基於上述結果, 現提醒醫生、藥劑師及其他衛生專業人士:

1. 當孕婦於懷孕第三期服用抗精神病藥物時, 注意胎兒可能吸收部分藥物, 而導致出生後的新生兒出現錐體外症狀或戒斷症狀。因此, 醫生應監測新生兒可能出現的錐體外症狀或戒斷症狀;
2. 對於正在服用抗精神病藥物的孕婦, 應對她們作風險-效益評估;
3. 由於可能出現嚴重的副作用, 對於將要懷孕的婦女, 提醒她們不要在沒有告知醫生的情況下, 自行停止服用抗精神病藥物, 對於正在懷孕的婦女, 亦不可突然停止服用抗精神病藥物。

藥物監測暨管理處

Result from the United States Food and Drug Administration(USFDA) postmarketing reviews on ADR reports up to October 2008 subsequent to the use of antipsychotics on pregnant mothers at their third trimester of pregnancy identified 68 cases of neonatal extrapyramidal signs(EPS) or withdrawal symptoms in newborns. Symptoms exhibited by the newborns include agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress and feeding disorder. In some of the exposed neonates EPS or withdrawal symptoms subsided within hours or days without treatment, while others may require hospital attention or even extended hospitalization. In light of the above we would recommend the following advice for physicians, pharmacists, and other healthcare professionals :

1. when antipsychotic medications were given to mothers at their third trimester of pregnancy, fetal exposure would predispose the neonates in developing EPS or withdrawal symptoms following delivery. Hence, clinicians should monitor neonates for EPS or withdrawal symptoms;
2. counsel patients about the benefits and risks of taking antipsychotic drugs during pregnancy;
3. remind them not to stop taking the antipsychotic medication without first talking to their physician if they are pregnant and not to abruptly stop their antipsychotic medication during pregnancy because this could cause significant complications in their treatment conditions.

Division of Pharmacovigilance  
and Pharmacoeconomics(DFF)

參考資料/Reference and website :

<http://www.fda.gov/Drugs/DrugSafety/ucm243903.htm>