



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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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: 關於特布他林(terbutaline)安全性的最新資訊

Ass./Subject: Latest safety update on terbutaline

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隨件附上一則關於特布他林(terbutaline)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 terbutaline. 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



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主題：關於特布他林(terbutaline)安全性的最新資訊

Subject : Latest safety update on terbutaline

美國食物及藥物管理局(USFDA)核准特布他林(terbutaline)用於治療和預防哮喘、支氣管炎以及肺氣腫引起的支氣管痙攣, 然而, terbutaline有時也會用於產科急症, 如早產和子宮過度收縮。USFDA評估了該藥的上市後數據, 認為對於孕婦, 長時間(超過48至72小時)注射或口服terbutaline引起母親死亡和嚴重心血管不良反應的風險超出其潛在的效益。基於上述原因, 現提醒醫生、藥劑師及其他衛生專業人士:

1. 注意孕婦長期使用口服或注射劑型的terbutaline曾有死亡和嚴重不良反應, 包括心率增加、暫時性高血糖、低血鉀、心律失常、肺水腫以及心肌梗塞)的個案出現;
2. Terbutaline的注射方案或連續輸注時間不應超過48至72小時, 此外, 不應於門診或家居中注射terbutaline;
3. 衛生專業人士應根據住院產科病人的具體情況, 決定注射terbutaline的效益是否高於風險;
4. 口服terbutaline禁用於預防和治療早產;
5. 提醒因患有其他疾病(如哮喘)而正在服用terbutaline的病人, 若準備懷孕或已懷孕, 須告知衛生專業人士。

備註: 獲准在本澳市場供應含特布他林(terbutaline)的口服和注射藥物包括 Bricanyl、Britaline、Eurobutal、Terbutine “Synco”、Terbuta “Christo”、Terbutaline “Jean-Marie”以及 Terbutaline “Quality”。

藥物監測暨管理處

Terbutaline, approved by United States Food and Drug Administration(USFDA) to treat and prevent bronchospasm associated with asthma, bronchitis, and emphysema, is sometimes also given in the acute obstetric conditions namely treating preterm labor and uterine hyperstimulation. After reviewing postmarketing reports, USFDA concluded that the risk of maternal death and serious cardiovascular adverse events outweighs any potential benefit to pregnant women receiving prolonged treatment with terbutaline injection(beyond 48-72 hour), or prolonged treatment with oral terbutaline. In view of the above, we recommend the following to physicians, pharmacists, and other healthcare professionals:

1. be aware that deaths and serious adverse reactions (increased heart rate, transient hyperglycemia, hypokalemia, cardiac arrhythmias, pulmonary edema, and myocardial ischemia) have been reported after prolonged administration of oral or injectable terbutaline to pregnant women;
2. injectable and continuous infusion-pump administration of terbutaline should not continue beyond 48 to 72 hours. In particular, injectable terbutaline should not be used in the outpatient or home setting;
3. healthcare professional may decide under certain obstetrical conditions when the benefit of using terbutaline injection for an individual patient in a hospital setting clearly outweighs the risk;
4. oral terbutaline is contraindicated for the treatment or prevention of preterm labor;
5. remind patients to talk to their healthcare professionals if they are taking terbutaline for another medical condition(e.g., asthma) while they are pregnant or become pregnant.

Note: The oral and injectable terbutaline authorized for distribution in the Macao market include Bricanyl, Britaline, Eurobutal, Terbutine “Synco”, Terbuta “Christo”, Terbutaline “Jean-Marie” and Terbutaline “Quality”.

Division of Pharmacovigilance
and Pharmacoeconomics(DFF)

參考資料/References and websites:

<http://www.fda.gov/Drugs/DrugSafety/ucm243539.htm>