



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: 關於含有drospirenone的口服避孕藥安全性的最新資訊

Ass./Subject: Latest safety update on drospirenone-containing oral contraceptives

頁數: 1/2

Nº folhas/N.pages:

隨件附上一則關於含有drospirenone的口服避孕藥安全性的最新資訊, 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, 亦可於非辦公時間致電63009255。

謹祝 台安!

Attached herewith is the latest safety update on drospirenone-containing oral contraceptives. 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 call 63009255.

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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近期兩篇發表於英國醫學雜誌的研究指出，相對於服用含levonorgestrel口服避孕藥的婦女，服用含drospirenone口服避孕藥的女性，出現靜脈血栓性事件(如深部靜脈栓塞和肺栓塞)的風險高出兩至三倍。Drospirenone是一種孕激素，與雌激素組成複方製劑用作口服避孕藥。美國食物及藥物管理局(USFDA)正評估這些研究的結果，以衡量含drospirenone口服避孕藥的風險及效益。目前，藥物監測暨管理處建議醫生、藥劑師及其他衛生專業人士：

1. 嚴格按照藥物說明書處方含有drospirenone的口服避孕藥；
2. 與病人討論含drospirenone口服避孕藥的效益及潛在的風險；
3. 教導病人認識深部靜脈栓塞和肺栓塞的症狀，如出現相關症狀時，應立即求診。

備註：獲准在本澳市場供應含有drospirenone的口服避孕藥包括Angeliq Tab、Yasmin Tab以及Yaz Tab。

藥物監測暨管理處

Two recent articles in the British Medical Journal reported a two to three fold greater risk of venous thromboembolic events (VTE, such as deep vein thrombosis (DVT) and pulmonary embolism (PE)) in women using oral contraceptives containing drospirenone rather than levonorgestrel. Drospirenone is a type of progestin used in combination with an estrogen in oral contraceptives. The United Food and Drug Administration (USFDA) is evaluating the conflicting results from these studies to fully assess the risks and benefits of drospirenone-containing birth control pills. Currently, Division of Pharmacovigilance and would like to advise physicians, pharmacists and health professionals that:

1. continue to follow the recommendations in the drug labels when prescribing oral contraceptive products that contain drospirenone;
2. discuss the known benefits and potential risks of drospirenone-containing products with your patients;
3. educate your patients to recognize the signs and symptoms of DVT and PE, and tell them to immediately contact their physician if they develop any of these symptoms.

Note : The drospirenone-containing oral contraceptives authorized for distribution in the Macao market include Angeliq Tab, Yasmin Tab and Yaz Tab.

Division of Pharmacovigilance
and Pharmacoeconomics(DFF)

參考資料/References and websites :

<http://www.fda.gov/Drugs/DrugSafety/ucm257164.htm>