



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 0809/DAF/11
Nº ref.

日期: 23/06/2011
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varenicline (Champix®)的安全性、risperidone (Risperdal®)和ropinirole (Requip®)的調配錯誤以及兒童服用paracetamol的劑量建議的最新資訊

Ass./Subject: Latest updates on safety of varenicline (Champix®), medication errors between risperidone (Risperdal®) and ropinirole (Requip®) and paracetamol dosing for children

頁數: 1/4

Nº folhas/N.pages:

隨件附上三則關於varenicline (Champix®)的安全性、risperidone (Risperdal®)和ropinirole (Requip®)的調配錯誤以及兒童服用paracetamol的劑量建議的最新資訊, 請各位參閱, 如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_wservlets_main.htm
- 郵寄 - 澳門士多利拜斯大馬路 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 are three latest updates on safety of varenicline (Champix®), medication errors between risperidone (Risperdal®) and ropinirole (Requip®) and paracetamol dosing for children. If any kind of adverse reaction is suspected 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_wservlets_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!

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

吳國良
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varenicline (Champix[®])的安全性、risperidone (Risperdal[®])和ropinirole (Requip[®])的調配錯誤以及兒童服用paracetamol的劑量建議的最新資訊

Subject：Latest updates on safety of varenicline (Champix[®]), medication errors between risperidone (Risperdal[®]) and ropinirole (Requip[®]) and paracetamol dosing for children

Varenicline (Champix[®])與心血管不良事件

根據一項在700位患有心血管疾病的吸煙人士中使用varenicline (Champix[®])或安慰劑的隨機、雙盲臨床試驗結果，雖然兩者在整體上發生心血管不良事件的機率不高，但相對服用安慰劑的病人，使用Champix[®]治療的病人會出現較多的包括心臟病發在內的突發病症。由於該項試驗在設計上未能對安全性的臨床指標作出具有統計學差異的結論，美國食物及藥物管理局(USFDA)將會繼續評估Champix[®]對心血管系統的風險。基於上述原因，藥物監測暨管理處提醒醫生、藥劑師及其他衛生專業人士：

1. 吸煙是引起心血管疾病的一項獨立及主要的危險因子，而Champix[®]有助於病人戒除煙癮。
2. 注意在患有心血管疾病並有使用Champix[®]的病人當中，曾有少許心血管不良事件的個案報道，當中包括心絞痛、非致死性的心肌梗塞以及外周血管疾病。
3. 對於患有心血管疾病的吸煙病人，如需處方Champix[®]，應衡量已知的效益及潛在的風險。
4. 對於獲處方Champix[®]的病人，教導他們若出現心血管疾病的症狀，如呼吸短促或困難、胸部疼痛、步行時腿部疼痛或這些症狀惡化時，需向醫生求診。

Risperidone (Risperdal[®]) 和 ropinirole (Requip[®])：因名稱相近引起的調配錯誤

Risperidone (Risperdal[®])是治療精神分裂症、雙極症以及自閉症相關的激動症等精神疾病的抗精神病藥物，ropinirole (Requip[®])是治療帕金森病和腿不寧綜合症的多巴胺激動劑。美國食物及藥物管理局(USFDA)關注有病人錯誤地獲發Risperdal[®]或Requip[®]的藥物調配錯誤的報告，某些服用了錯誤藥物的病人更需住院。兩藥混淆的原因是多方面的，包括：

1. 商品名和通用名皆相似。
2. 外包裝和標籤相似。
3. 錯誤地書寫處方。
4. 藥物特性的各種類同，如規格、劑型以及給藥間隔。

基於上述原因，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. 確保處方上列印的藥物名稱是清楚的。
2. 詢問病人關於獲處方的藥物，以確保病人知悉其用途，處方上含有藥物的治療用途可有助確保病人服用正確的藥物。
3. 不管藥物儲存在藥架上或任何地方，建議藥劑師將兩藥分開擺放。
4. 如處方不合理，或藥物名稱不清晰，藥劑師應向醫生確認。

Paracetamol:兒童服用paracetamol 更確切的劑量建議

英國藥物管理局(MHRA)近期建議更新兒童服用含有paracetamol液體製劑時的有關劑量，該建議更仔細地劃分年齡層，根據年齡層列出相應的劑量如下：



澳門特別行政區政府
Governo da Região Administrativa Especial de Macau
衛生局
Serviços de Saúde

規格	現行		建議	
	年齡	劑量	年齡	劑量
120mg/5mL	3個月至1歲	2.5mL	3至6個月	2.5mL
	1至6歲	5 至10 mL	6至24 個月	5mL
			2至4歲	7.5mL
			4至6歲	10mL
240或250 mg/5mL	6至12歲	5 至10 mL	6至8歲	5mL
			8至10歲	7.5mL
			10至12歲	10mL

上述建議是爲了確保兒童獲得與其年齡相應最合理的paracetamol劑量，並不是因爲現行採用的劑量存在安全性方面的問題。醫生仍可按照現行的劑量處方該藥，但應按照說明書的建議，不要超出每日建議服用的最大劑量。

藥物監測暨管理處

Varenicline (Champix®) and cardiovascular adverse events

A randomized, double-blind clinical trial of 700 smokers with cardiovascular disease who were treated with varenicline (Champix®) or placebo indicated while cardiovascular adverse events were infrequent overall, certain events, including heart attack, were reported more frequently in patients treated with Champix® than in patients treated with placebo. Owing to the trial was not designed to have statistical power to detect differences between the arms on the safety endpoints, the United States Food and Drug Administration (USFDA) is continuing to evaluate the cardiovascular safety of Champix®. In light of the above, Division of Pharmacovigilance and Pharmacoeconomics reminds physicians, pharmacists and other health professionals:

1. smoking is an independent and major risk factor for cardiovascular disease, and Champix® is effective in helping patients quit smoking.
2. be aware that a small of certain cardiovascular adverse events was reported in patients with cardiovascular disease receiving Champix®. The events included angina pectoris, nonfatal myocardial infarction and peripheral vascular disease.
3. weigh the known benefits of Champix® against the potential risks deciding to use the drug in smokers with cardiovascular disease.
4. counsel patients to seek medical attention if they experience new or worsening symptoms of cardiovascular disease while taking Champix® such as shortness of breath or trouble breathing, chest pain or pain in legs when walking.

Risperidone (Risperdal®) and ropinirole (Requip®): Medication errors due to name confusion

Risperidone (Risperdal®) is an antipsychotic medication used to treat mental illnesses including schizophrenia, bipolar disorder, and irritability associated with autistic disorder. Ropinirole (Requip®) is a dopamine agonist used in the treatment of Parkinson's disease and Restless Legs Syndrome. The United States Food and Drug Administration (USFDA) is alerting the public to medication error reports in which patients were given Risperdal® instead of Requip® and vice versa. In some cases, patients who took the wrong medication needed to be hospitalized. The causes of confusion between this two drugs are multi-factorial in nature including:



澳門特別行政區政府
Governo da Região Administrativa Especial de Macau
衛生局
Serviços de Saúde

1. similarities of both the brand and generic names.
 2. similarities of the container labels and carton packaging.
 3. illegible handwriting on prescriptions.
 4. overlapping product characteristics, such as the drug strengths, dosage forms, and dosing intervals.
- Therefore, Division of Pharmacovigilance and Pharmacoeconomics recommends physicians, pharmacists and other health professionals:

1. be sure to clearly print the drug name on written prescriptions.
2. counsel patients about their prescribed medication, making sure the patient understands its purpose. Including the medical reason for the medication on the prescription may help ensure the patient gets the correct medication.
3. pharmacists are advised to physically separate the stocks of these two drugs on the shelf or wherever they are stored.
4. pharmacists are advised to confirm the drug name with prescribers if the prescription is not legible or the drug name is not clearly stated.

Paracetamol: More exact paracetamol dosing for children to be introduced

British's Medicines and Healthcare products Regulatory Agency (MHRA) recently recommended an updated dosing for children's liquid medicines containing paracetamol. The updated dosing will have a larger number of narrower age bands and will define a single dose per age band listed below:

strength	current		recommended	
	age	dose	age	dose
120mg/5mL	3 months to under 1year	2.5mL	3-6 months	2.5mL
	1 year to under 6 years	5 to 10 mL	6-24 months	5mL
			2-4 years	7.5mL
			4-6 years	10mL
240 or 250 mg/5mL	6-12 years	5 to 10 mL	6-8 years	5mL
			8-10 years	7.5mL
			10-12 years	10mL

The recommendation is to ensure children get the most optimal dose of paracetamol suitable for their age not because of safety concerns the dosage currently applied. Doctors can still prescribe paracetamol following the current dosing and should follow the advice on the packaging, making sure not to exceed the recommended daily maximum dose.

Division of Pharmacovigilance
and Pharmacoeconomics(DFF)

參考資料/References and websites :

<http://www.fda.gov/Drugs/DrugSafety/ucm259161.htm>
<http://www.fda.gov/Drugs/DrugSafety/ucm258805.htm>
<http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON120251>