



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

簽署者/Ass./Signat.: 吳國良代廳長 Ng Kuok Leong – Acting Department Chief

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: 關於非典型抗精神病藥物和benzocaine安全性的最新資訊

Ass./Subject: Latest safety updates on atypical antipsychotics and benzocaine

頁數: 1/4

Nº folhas/N.pages:

隨件附上一則關於非典型抗精神病藥物和benzocaine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 are the latest safety updates on Latest updates on atypical antipsychotics and benzocaine. 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!

藥物事務廳代廳長

Acting Chief, Department of Pharmaceutical Affairs


吳國良

Ng Kuok Leong



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Subject：Latest safety updates on atypical antipsychotics and benzocaine

● 非典型抗精神病藥物與心血管風險

英國藥物監管局(MHRA)指出, 非典型(第二代)抗精神病藥物可能會增加精神分裂症病人心血管負擔的風險。當中指出, 罹患精神分裂症的病人, 其貿然死亡的風險是沒有患有精神病人人士的三倍, 而精神分裂症亦可能與引致心血管疾病及死亡的可修正或不可修正的危險因素有關(如吸煙、膳食差、久坐的生活模式、以及心血管疾病的家族史)。然而, 某些非典型精神病藥物亦可引起體重顯著增加、脂肪代謝紊亂和高血糖症, 當中以clozapine、olanzepine和quetiapine較易對病人造成上述代謝綜合症。最近CATIE臨床研究的結果指出, 雖然精神分裂症病人具有較高的心血管疾病和死亡風險, 但仍然忽略了治療代謝紊亂。因此, 當向病人處方非典型抗精神病藥物時, 建議醫生、藥劑師及其他衛生專業人士:

1. 評估和儘早判別病人所具有的可緩和的心血管危險因子和高血糖危險因子(如血壓升高、血脂升高、吸煙、腰圍增加等);
2. 每年監測精神分裂症病人的身體健康情況, 重點評估心血管的風險、血脂和血糖控制情況;
3. 定期檢查精神分裂症病人併發糖尿病和/或心血管疾病的情況;
4. 鼓勵和教育病人保持合適的健康飲食和定時運動習慣;
5. 只有在謹慎評估潛在的效益和對病人精神狀態的影響後, 才可改變原有的抗精神病藥物方案。

● Benzocaine噴霧劑、凝膠和液體與高鐵血紅蛋白血症

美國食物及藥物管理局(USFDA)於回顧多宗因使用benzocaine 噴霧劑引致高鐵血紅蛋白血症的個案後, 再次通知衛生專業人士關於手術中使用該藥的風險。高鐵血紅蛋白血症是罕見但嚴重的不良反應, 病人的血液攜氧能力大幅減少, 嚴重情況下可引致病人死亡。在相關個案中, 不良反應出現在所有含有benzocaine的外用劑型中, 包括噴霧劑、凝膠和液體製劑, 主要發生於兩歲以下使用benzocaine凝膠的牙科兒童病人。因此, 醫生、藥劑師及其他衛生專業人士須注意:

1. benzocaine噴霧劑用於口腔或喉部時具有引起高鐵血紅蛋白血症的潛在風險, 多為藥物使用疏失和不正確地使用 benzocaine噴霧劑, 如長時間施用或多於建議的使用頻率, 因此, 接受benzocaine噴霧劑的病人應使用最小的劑量, 以減少出現高鐵血紅蛋白血症的風險;
2. 病人如有呼吸問題, 如哮喘、支氣管炎或肺水腫、心臟疾病以及吸煙, 出現高鐵血紅蛋白血症的風險較高, 可考慮選擇其他治療方案;
3. 具有出現高鐵血紅蛋白血症風險的病人, 如4個月以下的小童和其他於受孕期間形成某些缺陷(如葡萄糖-6-磷酸脫氫酶缺乏症、血紅蛋白-M疾病、NADH高鐵血紅蛋白還原酶缺乏症以及丙酮酸激酶缺乏症)的病人, 可能較適合使用其他成份的藥物, 如lidocaine;
4. 接受benzocaine噴霧劑的病人應謹慎觀察高鐵血紅蛋白血症的症狀, 包括皮膚蒼白、變灰或變藍、頭痛、頭暈、呼吸短促、憂慮、疲倦和心跳加快, 這些症狀通常於使用含有benzocaine的外用製劑數分鐘至數小時內出現; 病人的糞便顏色改變(棕色或棕紅色)也可能是指徵之一, 但會較遲才出現;
5. 懷疑出現了高鐵血紅蛋白血症的病人應立即接受治療;
6. 該不良反應的出現可能與藥品的劑量、濃度和規格無關, 也與首次使用或重複使用無關;
7. 向病人作出建議:

- 父母或照護者不應對小童使用任何含有benzocaine的外用產品, 特別對於2歲以下的小童。如需使用, 應先諮詢醫生、藥劑師或護士的意見;
- 成年病人應依照產品說明書使用benzocaine凝膠或液體製劑舒緩口腔疼痛, 並將藥物儲存於小孩不能輕易拿到的地方。



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備註：獲准在本澳市場供應含有benzocaine的噴霧劑、凝膠和液體製劑包括Coracetin Otic和Otoceril Ear Drops Solution。

藥物監測暨管理處

- **Atypical antipsychotics and cardiovascular risks**

Atypical (second generation) antipsychotics may increase the burden of cardiovascular risks in schizophrenic patients as announced by the Medicine and Health-Products Regulatory Agency (MHRA), U.K. Accordingly, the risk of patients inflicted with schizophrenia who die prematurely from natural causes is three times the risk of those who are not mentally disturbed. Schizophrenia also seems to be associated with modifiable and non-modifiable risk factors for cardiovascular morbidity and mortality (e.g. smoking, poor diet, sedentary lifestyle, and family history of cardiovascular disease) which contribute for cardiovascular morbidity and mortality. Though some atypical antipsychotics are associated with significant weight gain, dyslipidemia, and hyperglycemia, individual drug namely clozapine, olanzepine and quetiapine does impart unique metabolic adverse effects onto individual patient. Latest results from the CATIE (Clinical Antipsychotic Trials of Intervention Effectiveness) study confirm that though schizophrenic patients may already have at an increased baseline risk of cardiovascular morbidity and mortality, they are still being undertreated for metabolic disorders. When atypical antipsychotic medications are planned for the patients, physicians, pharmacists and other healthcare professionals are advised that :

1. assessment and early identification of modifiable risk factors for individual patient e.g. cardiovascular and hyperglycemic (elevated blood pressure, raised lipid levels, smokers, increased waist measurement;
2. annual monitorization of the physical health of schizophrenic patients with emphasis on cardiovascular risk assessment, lipid modification and glycemic controls;
3. routine and scheduled consultations for schizophrenic patients comorbided with diabetes and/or cardiovascular diseases;
4. encouraging and educating patients as appropriate to maintain a healthy diet and regular exercise;
5. any change to the existing antipsychotic medication should only be based on careful assessment evaluating the potential benefits against the risks of destabilizing the mental state of the patients.

- **Benzocaine sprays, gels, liquids and methemoglobinemia**

United States Food and Drug Administration(USFDA) would like to notify healthcare professionals again about the danger of applying benzocaine containing sprays for medical procedures after reviewing cases of methemoglobinemia. Methemoglobinemia is a rare, but serious condition in which the amount of oxygen carried through the blood stream is greatly reduced. In the most severe cases, methemoglobinemia can result in death. Accordingly, this adverse effect has also been reported with all strengths of benzocaine containing topical preparations including sprays, gels and liquids, and cases occurred mainly in children aged two years or younger who were treated with benzocaine gel for teething. It is advised that physicians, pharmacists and other health professionals:

1. benzocaine sprays used in the mouth and throat can result in potentially dangerous levels of methemoglobinemia which are more likely due to medication errors and incorrect use of benzocaine sprays, e.g. longer duration or more frequent sprays than recommended. Hence, patients who receive benzocaine sprays should be given the minimum amount needed, to reduce the risks associated with methemoglobinemia;
2. patients who have breathing problems such as asthma, bronchitis, or emphysema, patients with heart disease, and patients who smoke are at greater risk for complications related to methemoglobinemia and may be candidates for other forms of therapy;



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3. patients who may have greater tendency for elevated levels of methemoglobinemia, such as all children less than 4 months of age and older patients with certain in-born defects (e.g. glucose-6-phosphodiesterase (G-6-PD) deficiency, hemoglobin-M disease, NADH-methemoglobin reductase deficiency, and pyruvate-kinase deficiency) may benefit from products with different active ingredients such as lidocaine;
4. patients who receive benzocaine sprays should be carefully observed for signs of methemoglobinemia including pale, gray or blue colored skin, headache, lightheadedness, shortness of breath, anxiety, fatigue and tachycardia (rapid heart rate). The above indicators which usually appear within minutes to hours of applying benzocaine containing topical products. A characteristic color of the blood (chocolate-brown rather than blood-red) can be a danger sign, but these changes are a late sign of the condition;
5. patients suspected of having high levels of methemoglobinemia should be promptly treated;
6. note that occurrence of this adverse reaction may not be related to the amount used, concentration strengths, whether the topical products is being used for the first time or after repeated applications;
7. advise your patients of the following:
 - parents or care-givers of young children especially younger than 2 years old should be instructed not to use any benzocaine related topical products on the children and talk to their doctors, pharmacists and nurses for any query;
 - adult consumers who use benzocaine gels or liquids to relieve pain in the mouth should follow the recommendations in the product label and store benzocaine products out of reach of children.

Note: The benzocaine containing products in sprays, gels and liquids available in Macau include Coracetin Otic and Otoceril Ear Drops Solution.

Division of Pharmacovigilance
and Pharmacoeconomics(DFF)

參考資料/References and websites :

<http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON111764>

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm250264.htm>