



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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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 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: 兩歲以下的小孩謹慎使用右美沙芬(dextromethorphan)

Ass./Subject: Cautious use of dextromethorphan in children less than two years old

頁數: 1/2

Nº folhas/N. pages:

隨件附上一則關於兩歲以下的小孩謹慎使用右美沙芬(dextromethorphan)的資料, 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 an update about cautioning use of dextromethorphan in children less than two years old. 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!

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

吳國良
Ng Kuok Leong



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主題：謹慎使用右美沙芬(dextromethorphan)於兩歲以下的小孩

Subject : Cautious use of dextromethorphan in children less than two years old

治療咳嗽藥物一般是通過直接抑制腦部咳嗽中樞而發揮作用，當中可待因(codeine)和右美沙芬(dextromethorphan)是咳嗽治療藥的常用成份之一。右美沙芬具有與codeine相當的止咳效果，但不具有止痛作用，一般情況下是安全和易耐受的，然而當右美沙芬的劑量超出10mg/kg時，可能會出現嚴重毒性反應，包括呼吸抑制。由於基因的差異性，約有10%的人士對右美沙芬的酶降解代謝較慢，從而產生血藥濃度過高及造成危險的情況。右美沙芬的不良反應雖然罕見，但包括嘔吐在內的胃腸不適、嗜睡和頭暈時有發生。目前，文獻並沒有收載右美沙芬用於兩歲以下小孩的正規治療方案。

基於右美沙芬在兩歲以下兒童的劑量還未確定，且該藥物用於兩歲以下小孩的安全性還未證實，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. 應儘量避免處方右美沙芬於兩歲以下的兒童病人，倘必要時，醫生應根據臨床情況謹慎作風險效益評估，並按個體需要訂定用藥劑量。
2. 提醒兒童的家長和照護者須嚴格依從醫生指示服用含有右美沙芬的藥物，如出現不良反應，須立即就診。
3. 提醒市民右美沙芬屬醫生處方藥物，須嚴格依照醫囑服用。

藥物監測暨管理處

Antitussives elicit their clinical effect by directly inhibiting the cough center in the brain, of which codeine and dextromethorphan are compounds found in cough medicines. Dextromethorphan has equal antitussive effects as codeine but does not possess analgesic property. It is generally safe and well tolerated, but serious toxicity including respiratory distress can be seen at doses of 10 mg/kg or greater. Approximately 10% of the population are slow metabolizers of dextromethorphan, owing to a genetic polymorphism for its enzymatic degradation, the plasma concentration of the medication in this group of patients will be elevated, placing them at higher risk. Adverse effects with dextromethorphan are rare, but nausea and/or other gastrointestinal disturbances, slight drowsiness, and dizziness sometimes occur. Currently, it is not well documented that dextromethorphan being regularly used in children <2 years of age.

Since the absence of dosing recommendations of dextromethorphan and the safety has not been established in children less than 2 years old, Division of Pharmacovigilance and Pharmacoeconomics would like to recommend the following important messages for physicians, pharmacists, and other healthcare professionals:

1. physicians should avoid prescribing dextromethorphan-containing medication for pediatric patients less than 2 years old unless, otherwise, absolutely necessary after cautious clinical valuation validating benefit over risk. In situation that warrants such use, dosage of dextromethorphan for this group of patients must be individualized.
2. remind parents and caregivers to strictly adhere and follow the instructions as given by the prescribers when administering dextromethorphan-containing medication to their children. Seek for immediate medical attention in case of adverse reactions.
3. remind the public that as dextromethorphan is classified as Prescription Medication Only (PMO), ensure strict adherence to the instructions as given by the prescribers when administering dextromethorphan-containing medication.

Division of Pharmacovigilance
and Pharmacoeconomics(DFF)

參考資料/References and website :

1. Current Opinions in Pediatrics 2006, 18: 184-188, p. 185
2. Dynamed.com - <http://dynaweb.ebscohost.com/Detail?id=AN+233183&sid=878644f3-afe9-4451-9913-c3b9802f0f61@sessionmgr11>