



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 0378/DAF/10  
N° ref.

日期: 29/04/2010  
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:

Para/To 部門/Dept.:

收件人/Att.-C/O:

傳真機/Fax:

主題: 關於鹽酸異丙嗪注射液(promethazine hydrochloride injection)安全性的最新資訊

Ass./Subject: Latest safety update on promethazine hydrochloride injection

頁數: 1/3

N° folhas/N.pages:

加拿大衛生部(Health Canada)通知衛生專業人士關於抗組胺藥物鹽酸異丙嗪注射液(promethazine hydrochloride injection)安全性的最新資訊, 當中要求在藥物說明書中增加以下內容:

1. 兒童病人出現的呼吸抑制

由於有可能出現致命的呼吸抑制, 鹽酸異丙嗪注射液不應用於 2 歲以下的兒童病人。在藥物上市後的通報個案中, 曾有 2 歲以下兒童病人出現呼吸抑制, 其中包括致命的個案; 對於 2 歲以上的兒童的病人, 也應謹慎使用該藥。因此, 建議衛生專業人士使用最低有效劑量, 以及避免併用其他可能減弱呼吸功能的藥物。

2. 嚴重組織損傷(包括壞疽)

不管何種注射途徑, 鹽酸異丙嗪注射液都可能產生嚴重的化學刺激, 以及對組織造成損傷, 這些刺激及損傷是由於藥物血管外滲、不經意的動脈內注射以及神經內/外的浸潤所造成。其不良反應包括灼傷、疼痛、血栓性靜脈炎、組織壞死以及壞疽。在某些個案中, 需要採取外科措施, 包括筋膜切開、皮膚移植及/或截肢等。

3. 基於靜脈注射具有一定風險, 深部肌肉注射是鹽酸異丙嗪注射液的最佳給藥途徑, 但禁止以皮下注射給藥。不管在甚麼部位注射, 鹽酸異丙嗪注射液偶然都會造成化學刺激, 在非常罕見的情況下, 注射部份可出現壞疽等嚴重的組織損傷。衛生專業人士應教育病人, 如感到注射部位出現持續或惡化的疼痛及灼傷感覺時, 須及時告知醫生。

醫生、藥劑師或其他衛生專業人士如懷疑由鹽酸異丙嗪注射液(promethazine hydrochloride injection)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](http://www.ssm.gov.mo/design/webservices/c_wservlets_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



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

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](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！

Health Canada notified healthcare professionals about the revised labelling of promethazine hydrochloride injection, an antihistamine medication, requiring the following information added to the drug leaflet:

1. Respiratory depression in pediatrics

Promethazine hydrochloride injection should not be used in pediatric patients less than 2 years of age because of the potential for fatal respiratory depression. Post-marketing cases of respiratory depression, including fatalities, have been reported with use of promethazine in pediatric patients less than 2 years of age. Caution should be exercised when administering promethazine hydrochloride injection to pediatric patients 2 years of age and older. Health care professionals are recommended to use the lowest effective dose, and concomitant use of drugs that may also slow down the breathing mechanism should be avoided.

2. Severe tissue injury, including gangrene

Promethazine hydrochloride injection can cause severe chemical irritation and damage to tissues regardless of the route of administration. Irritation and damage can result from perivascular extravasation, unintentional intra-arterial injection, and intraneuronal or perineuronal infiltration. Adverse reactions include burning, pain, thrombophlebitis, tissue necrosis, and gangrene. In some cases, surgical intervention, including fasciotomy, skin graft, and/or amputation have been required.

3. Due to the risks of intravenous injection, the preferred route of administration of promethazine hydrochloride injection is deep intramuscular injection. Subcutaneous injection is contraindicated. Regardless of the body parts where the drug is injected, promethazine has the potential to occasionally cause chemical irritation and in rare cases severe tissue damage at the site of injection, including cases of gangrene. Healthcare professionals should encourage their patients to immediately report any persistent or worsening pain or burning sensation they feel at the site of injection.

If physicians, pharmacists or other healthcare professionals suspect any kind of adverse reaction subsequent to the use of promethazine hydrochloride injection or any other medication, please report through any of the following methods :

- Online - [http://www.ssm.gov.mo/design/webservices/c\\_wservices\\_main.htm](http://www.ssm.gov.mo/design/webservices/c_wservices_main.htm)
- Mail to - 51 Avenida do Sidonio Pais, Edificio China Plaza, 2<sup>nd</sup> Floor, Macao S.A.R., China
- Fax to - 853-28524016



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

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](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 of Department of Pharmaceutical Affairs

吳國良  
Ng Kuok Leong

參考資料/Reference and website :

[http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/\\_2010/2010\\_58-eng.php#note](http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2010/2010_58-eng.php#note)

<http://webprod.hc-sc.gc.ca/dpd-bdpp/info.do?lang=eng&code=5089>