



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

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致:

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主題: 關於抗甲狀腺素藥物propylthiouracil安全性的最新資訊
Ass./Subject: Latest safety update on the antithyroid propylthiouracil.
頁數: 1/3

Nº folhas/N.pages:

美國食物及藥物管理局（USFDA）通知衛生專業人士一則關於抗甲狀腺素藥物 propylthiouracil(PTU)安全性的最新資訊。資料顯示，曾有服用上述藥物的病人出現嚴重肝損傷、急性肝衰竭甚至死亡的個案，這些病人包括成人及兒童。最新的安全性警告指出，對於患甲狀腺機能亢進的病人，應在不能耐受其他治療方案時(如使用methimazole、接受放射性碘或手術)，才可使用propylthiouracil。

USFDA提醒衛生專業人士注意該藥最新的安全性資訊，以及依照藥物的說明書使用該藥。基於相同考慮，衛生局藥物事務廳通知本澳的醫生及藥劑師以下資訊：

- 曾有服用上述藥物的病人出現嚴重肝損傷、急性肝衰竭甚至死亡的個案，這些病人包括成人及兒童。
- 對於甲狀腺機能亢進的病人，應在不能耐受其他治療方案時(如使用methimazole、接受放射性碘或手術)，才可使用propylthiouracil。
- 因為於懷孕首三個月期間使用methimazole曾發現胎兒畸型個案，因此當懷孕首三個月的婦女需要使用抗甲狀腺藥物時，可選擇使用PTU。
- 除了在其他治療方案不適用的情況下，一般並不建議PTU用於兒童病人。
- 細閱該藥的說明書以及了解使用PTU的完整資訊，以為病人及其照護者提供適當的資訊：
 - i 提醒病人依照醫生指示服藥。
 - ii 對於懷孕首三個月(1至12周)的甲亢病人，可選用PTU治療。正在服用PTU或其他抗甲狀腺藥物的婦女，如已經懷孕或計劃懷孕，應諮詢醫生的意見。
 - iii 如病人於服用PTU出現發熱、食慾減退、噁心、嘔吐、疲倦、瘙癢、尿液變黑或皮膚及眼睛變黃，應聯絡醫生或藥劑師。



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- iv 教導有關病人通知醫生或藥劑師其正在服用的其他藥物以及併有的疾病。
- v 告知病人不要在未經醫生同意下停止使用PTU或其他抗甲狀腺藥物。

閣下可親臨，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！

The United States Food and Drug Administration (USFDA) notified healthcare professionals about the added Boxed Warning on the label of propylthiouracil (PTU), an antithyroid medication. Reports of severe liver injury and acute liver failure, some of which have been fatal, in adult and pediatric patients using this medication were included into this section. The new warning also states that for patients being started on treatment for hyperthyroidism it may be appropriate to reserve use of propylthiouracil for those who cannot tolerate other treatments such as methimazole, radioactive iodine or surgery.

With the above information, USFDA reminded healthcare professionals to be aware of this new safety information and adhere to the recommendation on the drug label. In congruence with the Agency's additional advice, the Department of Pharmaceutical Affairs, Health Bureau would like to re-iterate the following information for our local physicians and pharmacists:

- be aware that severe liver injury and acute liver failure, including fatal cases, that have been reported in adult and pediatric patients taking PTU.
- before initiating a patient on hyperthyroid treatment, PTU should be reserved for patients who cannot tolerate methimazole or for patients for whom radioactive iodine therapy or surgery is not an appropriate treatment.
- PTU may be the treatment of choice when an antithyroid drug is needed during and just prior to the first trimester of pregnancy. Fetal abnormalities have been seen with methimazole use during the first trimester of pregnancy.
- PTU is not recommended for use in pediatric patients, except in rare instances during which other alternative treatments are inappropriate.
- review the updated information on the drug label and understand the complete information on the use of PTU so that you can counsel the patients or care-takers when they are picking up the prescription :
 - i remind them to follow the direction of use as given.
 - ii for female patients notify them that PTU may be the treatment of choice during and just before the first trimester of pregnancy (weeks 1-12). Consult with their prescribing physician for advice if they are pregnant or have plan to become pregnant while on PTU or other antithyroid medicines.



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- iii instruct them to contact their physician or pharmacist if they experience fever, loss of appetite, nausea, vomiting, tiredness, itchiness, dark-colored urine, or yellowing of your skin or eyes while on PTU.
- iv educate and familiarize the patients to notifying their attending physician and pharmacist about any medication they are taking or the medical conditions they may have.
- v notify them NOT to stop taking PTU or any antithyroid medication without talking with their physician or pharmacist.

If physicians, pharmacists or other healthcare professionals suspect any kind of adverse reaction subsequent to the use of propylthiouracil or any antithyroid 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!

藥物事務廳廳長
Chief, Department of Pharmaceutical Affairs

蔡炳祥
Choi Peng Cheong

參考資料/Reference and website for downloading the PTU Medication Guide :
<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm209023.htm>
<http://www.fda.gov/downloads/Drugs/DrugSafety/UCM208533.pdf>