衛生局　藥物事務廳

季度藥訊 Quarterly Drug Newsletter

2009　No. 3

本季度藥訊的內容主要摘錄自世界各國藥政部門所公佈及在本澳所收集有關藥物安全性的資訊，目的是通知本澳的衛生專業人士最新的藥物安全性資訊，從而推廣安全及合理用藥。

The content of this Quarterly Drug Newsletter originates as compilation of the adverse drug reactions (ADR) and drug safety issues published by various drug regulatory authorities as well as those reported locally. With this information, we aim at disseminating the latest adverse drug reaction alerts, safety and efficacy issues to our healthcare professionals with the ultimate goal to encourage safe and rational use of pharmaceuticals.

熱點關注藥物 ***DRUGS OF CURRENT INTEREST***

熱點關注藥物泛指一些近期在國內外及本地曾被報告發生藥物不良反應的藥物，以及最近獲批准進口本澳的新藥，訂定熱點關注藥物的目的是提醒衛生專業人士尤其關注及通報該等藥物所引起的不良反應，如　閣下察覺病人在服用以下及其他藥物後產生任何不良反應，請向藥物事務廳通報。

Generally speaking, ¡Drugs of Current Interest¡ are defined as those drugs of which adverse drug reaction(s) (ADRs) was (were) experienced and had been reported recently at international, national and local levels. In addition, drugs that have received recent approval for importation into Macao are also being incorporated into this list. The purpose of including this column serves to remind all healthcare professionals to pay special attention to ADRs and report them. If you observe any adverse reaction on your patient subsequent to the use of the following or any other drugs, please report all suspected reactions to the Department of Pharmaceutical Affairs.

Abacavir	Drotrecogin alfa	Methylphenidate
Adalimumab	Entecavir	Metoclopamide
Aliskiren	Erlotinib	Moxifloxacin
Allopurinol	Eszopiclone	Metoclopamide
Atorvastatin	Etanercept	Moxifloxacin
Bisphosphonates	Etoricoxib	Mycophenolate mofetil
Bevacizumab	Ezetimibe	Norfloxacin
Botulinum toxins	Ezetimibe/Simvastatin	Oseltamivir
Bortezomib	Flucloaxillin	Phenytoin
Carbamazepine	Fluoroquinolones	Propranolol
Carbimazole	Fosaprepitant dimeglmine	Raltegravir
Certolizumab pegol	Fulvestrant	Rimonbant
Clopidgrel	Gadobenate dimeglumine	Rituximab
Darunavir	Heparin sodium	Rosiglitazone
Decitabine	Iloprost trometamol	Simvastatin
Deferasirox	Infliximab	Sunitinib malate
Desflurane	Ivabradine	Tinzaparin sodium
Dextropropoxyphene (DXP)	Lamotrigine	Tiotropium bromide
Diacerein	Lapatinib	Trabectedin
Didanosine	Levofloxacin	Zanamuvir
Docetaxel	Leukotriene inhibitors ¡ montelukast	Zonisamide

通報及聯絡資料 ***Reporting and Contact Information:***

通報表格：在 http://www.ssm.gov.mo/design/services/serpt_chn.pdf 下載或向藥物事務廳索取。
網上通報：登入 http://www.ssm.gov.mo。
如有任何疑問，請致電 85983517(辦公時間)或傳呼 85008068(非辦公時間)。
Report form: access http://www.ssm.gov.mo/design/services/serpt_chn.pdf to download or obtain from Dept. of Pharmaceutical Affairs. Internet reporting: access http://www.ssm.gov.mo. Any query, call 85983517(office hrs) or pager 85008068 (off-duty hrs).

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有關 **varenicline (ChantixR, ChampixR)** 及 **bupropion (ZybanR, WellbutrinR)**安全性的最新資訊

Latest safety updates on varenicline (ChantixR, ChampixR) and bupropion (ZybanR, WellbutrinR)

資料來源: 美國食物及藥物管理局
Source： United States Food and Drug Administration (USFDA)
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm170090.htm
http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/ucm169988.htm
http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm169986.htm
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm170100.htm

美國食物及藥物管理局（USFDA）曾於 2007 年發出有關戒煙藥 varenicline (ChantixR, ChampixR)的安全性資訊後，近期 USFDA 再次通知衛生專業人士一則有關戒煙輔助藥物 varenicline 及 bupropion (ZybanR, WellbutrinR)安全性的資訊，該局已要求製造商在上述藥物的說明書上增印加框警告內容，以強調使用這些藥物後所引致嚴重神經症狀的風險，當中包括行爲改變、敵對、激動、情緒鬱結、出現自殺念頭與行爲以及企圖自殺。上述新增警告資訊是基於 USFDA 對 varenicline 及 bupropion 不良事件通報的持續監測結果而發出的，報告指出病患在服用 varenicline 或 bupropion 後引發自殺事件具有時間關聯性，且令一些從未患有精神病病史的患者產生自殺意念及自殺行爲。

基於以上所述，建議醫生、藥劑師及其他衛生專業人士提醒病人，如出現有別於典型尼古丁戒斷症狀的情緒激動、鬱結、行爲改變，或產生自殺念頭與行爲，應停服 varenicline 或 bupropion，並立刻向醫生求診。

Further to the issuance of a safety alert on smoking cessation medication varenicline (ChantixR, ChampixR) in 2007, the United States Food and Drug Administration (USFDA) notified healthcare professionals once again about the latest safety update on the smoking cessation aids varenicline (ChantixR, ChampixR) and bupropion (ZybanR, WellbutrinR & generics). She has required the manufacturers of these drugs to add new Boxed Warnings highlighting the risk of serious neuropsychiatric symptoms in patients using these products. These symptoms include changes in behavior, hostility, agitation, depressed mood, suicidal thoughts and behavior, and attempted suicide. The added warnings are based on the continued review of postmarketing adverse event reports for varenicline and bupropion received by the FDA. These reports included those with a temporal relationship between the use of varenicline or bupropion and suicidal events and the occurrence of suicidal ideation and suicidal behavior in patients with no history of psychiatric disease.
In light of the above, we would like to inform all physicians, pharmacists and other healthcare professionals to advise patients to stop taking varenicline or bupropion and contact their prescribers immediately if they experience agitation, depressed mood, and any changes in behavior that are not typical of nicotine withdrawal symptoms, or if they experience suicidal thoughts or behavior.

有關甘精胰島素 **(insulin glargine,** 商品名：**Lantus^{R})**安全性的最新資訊

Latest safety update on insulin glargine (Lantus^{R})

資料來源：美國食物及藥物管理局
歐盟藥物監管局
Sources： United States Food and Drug Administration (USFDA)
European Medicine Agency (EMEA)
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm170089.htm
http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm169722.htm
http://www.emea.europa.eu/humandocs/PDFs/EPAR/Lantus/40847409en.pdf

美國食物及藥物管理局（USFDA）及歐盟藥物監管局(EMEA)通知衛生專業人仕一項有關胰島素類似物（尤指甘精胰島素，商品名：Lantus^{R}）安全性的最新資訊。在最新公佈有關糖尿病病人使用 Lantus^{R}後可產生致癌風險的四項觀察性研究中，有三項顯示會增加該類病人患癌的風險。根據現有數據，上述監管機構建議病人不應在未諮詢醫生的情況下擅自停用胰島素治療，因血糖值控制不當會令病人產生即時及長期性的嚴重不良影響。此外，爲了進一步了解 Lantus^{R}與致癌的關聯性，上述監管機構正評估從各方面收集到有關 Lantus^{R}的安全性數據，並在得出結果後向公眾公佈。本廳會密切監測該藥的安全性及密切注意上述監管機構針對 Lantus^{R}之評估結果，並會將最新結果通知衛生專業人士。

The United States Food and Drug Administration (USFDA) and European Medicine Agency (EMEA) notified healthcare professionals about the latest safety update on the insulin analogues, in particular insulin glargine (Lantus^{R}). Latest data indicated that, three out of the four recently-published observational studies describing the use of insulin glargine (Lantus^{R}) in diabetes, may pose a possible increased risk for cancer development with these patients. Based on the currently available data, the agencies recommend that patients should not stop taking their insulin therapy without consulting a physician, since uncontrolled blood sugar levels can cause both immediate and long-term serious adverse effects. Meanwhile, the agencies are currently reviewing safety data on Lantus^{R} from many sources in order to better understand the risk, if any, for cancer associated with the use of Lantus^{R}. They will inform the public once the final results are concluded. Department of Pharmaceutical Affairs will keep a close vigilance and attention on the safety and results of the agencies¡ assessments on Lantus^{R} and we will inform all healthcare professionals once the latest update is available.

有關 **omalizumab**（商品名：**Xolair^{R}**）安全性的最新資訊

Latest safety update on omalizumab（**Xolair^{R}**）

資料來源：美國食物及藥物管理局
Source： United States Food and Drug Administration (USFDA)
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm172406.htm

美國食物及藥物管理局（USFDA）通知衛生專業人士一則有關 omalizumab（商品名：Xolair^{R}）安全性的最新資訊。該局正評估一份有關 omalizumab（Xolair^{R}），名稱爲¡Evaluating the Clinical Effectiveness and Long-Term Safety in Patients with Moderate to Severe Asthma (EXCELS)¡的安全性持續研究的報告，當中發現，相較於沒有使用 Xolair^{R}的對照組，使用該藥的病人產生缺血性心臟病、心律不整、心肌病變、心衰竭、肺部高血壓、腦血管疾病以及栓塞性、血栓性和血栓靜脈炎不良事件的比例較高。Xolair^{R}獲批准用於那些對常年空氣過敏測試呈陽性反應且接受吸入性類固醇治療無效的中度至重度持續性哮喘的成人與青少年(12 歲及以上)病人。該局目前不會對 Xolair^{R}的說明書作出修改，亦不建議病患停用 Xolair^{R}，但提醒衛生專業人士在 EXCELS 研究評估報告完成前，應注意說明書中有關使用該藥的風險及好處，同時亦應留意上述關於心血管及腦血管不良反應風險的最新訊息。本廳會密切監測上述藥物的安全性及密切注意上述監管機構針對 omalizumab 的評估結果，並會將最新結果通知衛生專業人士。

The United States Food and Drug Administration (USFDA) notified healthcare professionals about the latest update on omalizumab (Xolair^{R})**.** The Agency is evaluating interim safety findings from an ongoing study of omalizumab (Xolair^{R}) titled ¡ Evaluating the Clinical Effectiveness and Long-Term Safety in Patients with Moderate to Severe Asthma¡ (EXCELS) that suggests a disproportionate increase in ischemic heart disease, arrhythmias, cardiomyopathy and cardiac failure, pulmonary hypertension, cerebrovascular disorders, and embolic, thrombotic and thrombophlebitic events in patients treated with Xolair^{R} compared to the control group of patients not given the drug. Xolair^{R} is approved for use by adults and adolescents (12 years of age and above) with moderate to severe persistent asthma who test positive for reactivity to a perennial airborne allergen, and whose symptoms are inadequately controlled with inhaled corticosteroids. USFDA is not recommending any changes to the prescribing information for Xolair^{R} and is not advising patients to stop taking Xolair^{R} at this time. Until the evaluation of the EXCELS study is completed, healthcare professionals need to be aware of the risks and benefits described in the prescribing information, as well as the new information from the ongoing EXCELS study that may suggest a risk of cardiovascular and cerebrovascular adverse events. Department of Pharmaceutical Affairs will keep a close vigilance and attention on the safety and results of the above Agency¡s assessments on Xolair^{R}and we will inform all healthcare professionals once the latest update is available.

有關奧斯他韋 **oseltamivir** （商品名：特敏福^{R}, **Tamiflu**^{R}）引發神經精神性不良事件的最新資訊

Latest update on neuropsychiatric adverse events associated with oseltamivir (Tamiflu^{R})

資料來源： 星加坡藥監局
Source ： Singaporean Health Sciences Authority (HSA)
http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/safety_information/DHCPL.html

星加坡藥監局（HSA）通知衛生專業人士一則有關服用奧斯他韋oseltamivir（商品名：特敏福^{R}, Tamiflu^{R}）後引發神經精神性不良事件的資訊。據述，該局轄下的藥物監測單位近期接獲3宗與奧斯他韋有關不良事件的通報個案，當中患者產生迷惑感(disorientation)、說話語無倫次(incoherent speech)、幻覺(hallucination)及自殺企圖(suicidal attempts)的症狀。雖然目前仍未清楚了解這些事件是否直接與奧塞米韋有關，但HSA通知衛生專業人士須警惕該藥可引發神經精神性事件，並應通知照顧年輕患者的人士上述不良事件的潛在風險。本廳到目前爲止並沒有接獲關於oseltamivir不良反應的本地通報個案，但會密切留意其他監管機構發出針對服用oseltamivir後引發神經性精神病變不良事件的報告，並會將最新資訊通知衛生專業人士。

The Singaporean Health Sciences Authority (HSA) notified healthcare professionals about the reported cases on neuropsychiatric adverse events associated with oseltamivir (Tamiflu^{R}). Accordingly, the Pharmacovigilance Branch (PVB) of HSA recently received 3 local reports concerning the association of oseltamivir with the development of the above adverse events, whereby patients experienced symptoms of disorientation, incoherent speech, hallucination and suicidal attempt suspected to be associated with oseltamivir. Although it is unclear if the causality of these events is directly due to oseltamivir, HSA advises healthcare professionals to be aware of these neuropsychiatric events and to advise caregivers of young patients of the potential risk of these events. Until this present moment Department of Pharmaceutical Affairs has not received any local drug adverse reaction report about oseltamivir. We will closely monitor on reports issued by the other regulatory agencies concerning neuropsychiatric adverse events that are suspected to be linked with oseltamivir (Tamiflu^{R}), and will inform all healthcare professionals once the latest update is available.

有關 **orlistat**（商品名：賽尼可^{R}**, Xenical**^{R}）安全性的最新資訊

Latest safety update on orlistat (Xenical^{R}）

資料來源：美國食物及藥物管理局
Source ：The United States Food and Drug Administration (USFDA)
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm180025.htm
http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm179166.htm

美國食物及藥物管理局（USFDA）通知衛生專業人士一則有關 orlistat （商品名：賽尼可^{R}, Xenical^{R}）可能引發肝臟不良事件的最新資訊。自 1999 年至 2008 年 10

月十年期間，USFDA 共接獲 32 宗有關病人在服用 orlistat 後產生嚴重肝臟受損的通報，當中包括 6 宗肝衰竭的個案。上述 32 宗嚴重肝臟受損的個案中，最常見的不良反應包括黃疸、虛弱及腹痛。該局正審查及分析由製藥廠所提供有關肝臟受損疑似個案的其他數據。直至目前爲止，仍未能確立 orlistat 與肝臟受損的關聯性。USFDA 並非建議衛生專業人士更改其處方 orlistat 的做法，現正服用 orlistat 的病人應繼續按處方指示服用該藥，如出現任何可能與 orlistat 有關的肝臟損傷相關症狀，尤其是身體虛弱或疲累、發熱、黃疸或尿液呈棕色等，即向醫生求診。其他肝臟損傷的症狀亦包括腹痛、噁心、嘔吐、糞便色澤轉淺、發癢或食慾不振。本廳目前並沒有接獲因服用 orlistat 後引發藥物不良反應的本地通報個案，但會密切監測其他監管機構針對服用 orlistat 後引發與肝臟不良事件的報告，並會將最新資訊通知各衛生專業人士。

The United States Food and Drug Administration (USFDA) notified healthcare professionals on liver-related adverse events associated with orlistat (Xenical^{R})**.** USFDA had received 32 reports of serious liver injury, including 6 cases of liver failure, in patients using orlistat between 1999 and October 2008. The most commonly reported adverse events described in the 32 reports of serious liver injury were jaundice, weakness, and abdominal pain. The Agency is reviewing other data on suspected cases of liver injury submitted by the manufacturers of orlistat, analysis of these data is ongoing and no definite association between liver injury and orlistat has been established at this time. USFDA is not advising healthcare professionals to change their prescribing practices with orlistat. Patients currently taking orlistat should continue to take it as prescribed and consult their prescribing physician if they are experiencing symptoms possibly associated with the use of orlistat and development of liver injury, particularly weakness or fatigue, fever, jaundice or brown urine. Other symptoms may include abdominal pain, nausea, vomiting, light-colored stools, itching, or loss of appetite. Until this present moment Department of Pharmaceutical Affairs has not received any local drug adverse reaction associated with orlistat, we will closely monitor on reports issued by the other regulatory agencies concerning liver-related adverse events that are suspected to be linked with orlistat, and will inform all healthcare professionals once the latest update is available.

有關氯吡格雷和質子泵抑制劑安全性的最新資訊

Latest safety update on clopidogrel and proton pump inhibitors (PPIs)

資料來源：美國食物及藥物管理局
歐洲藥監局
Medscape 期刊

Sources ：The United States Food and Drug Administration (USFDA)
European Medicines Agency (EMEA)
Medscape Journal

http://www.fda.gov/medwatch/safety/2009/safety09.htm#plavix
http://www.fda.gov/cder/drug/early_comm/clopidogrel_bisulfate.htm
http://www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/CON051770
http://www.medscape.com/viewarticle/709133?src=mp&spon=30&uac=81564HV

繼 2009 年 1 月美國食物及藥物管理局(USFDA)公佈氯吡格雷(clopidogrel bisulphate)(柏域斯R, PlavixR)和質子泵抑制劑(PPI)併用時會降低 clopidogrel 的療效後，今年 6 月歐洲藥監局轄下的人用藥物委員會也得出併用上述藥物時 clopidogrel 的治療效果減少的結論，並建議除非絕對需要，否則不建議 clopidogrel 與 PPI 同時使用。資料顯示通過肝內細胞色素 P450(CYP)的 CYP2C19 異構酶代謝的 clopidogrel，其抗血小板作用會被特定的 PPIs 減弱。有些 PPIs 如奧米拉唑(omeprazole)和它的 S-異構物 esomeprazole(Nexium$^{@}$)，可抑制 CYP2C19 異構酶，因此減少 clopidogrel 的抗血栓作用。另外，現有臨床研究顯示，由於 CYP2C19 基因的多形性導致此酶活性減弱也可能降低 clopidogrel 的效果。而約有 30%的白人、40%的非裔人及 55%的東亞裔人帶有此 CYP2C19 多形性的基因。

在有進一步資料前，醫生應審慎作臨床判斷，只有高危病人才考慮同時處方 PPIs 與 clopidogrel。基於新的證據，clopidogrel 的製造商不鼓勵它與 omeprazole 併用，醫生如認爲有需要對胃部作出保護，可以考慮使用組胺 II 型受體阻斷劑如雷尼替丁(ranitidine)或法莫替丁(famotidine)作爲第一綫用藥。

Subsequent to the United States Food and Drug Administration¡s (USFDA) announcement on January 2009 describing a drug interaction between clopidogrel bisulfate (PlavixR) and proton pump inhibitors (PPI) when given concurrently would reduce the therapeutic effectiveness of clopidogrel. On June this year the Committee for Medicinal Products for Human Use (CHMP) under the European Medicine Agency (EMEA) also concluded the above observation and recommended against concomitant use of a PPI and clopidogrel unless absolutely necessary. Evidence suggests that certain PPIs reduce the antiplatelet effects of clopidogrel, which was being metabolized within the liver through the cytochrome P450 (CYP) class CYP2C19 isoenzyme. Those PPIs, such as omeprazole and its S-enantiomer esomeprazole (Nexium^{R}), are thought to inhibit the CYP2C19 isoenzyme, thus negating the antithrombotic effects of clopidogrel. Additional clinical studies indicated that the effectiveness of clopidogel is diminished in patients with a polymorphism of the CYP2C19 allele that results in reduced activities of this enzyme. An estimated 30% of whites, 40% of blacks, and over 55% of East Asians are carriers with polymorphism of the CYP2C19 allele.
Until further data is available physicians should exercise clinical judgment cautiously and only recommend that high risk-patients to receive PPIs together with clopidogrel. Manufacturer of clopidogrel discourages its concurrent use with omeprazole on the basis of the new evidence. If gastroprotection is deemed appropriate, consider using histamine-2 blockers such as ranitidine or famotidine as first-line therapy.

有關別嘌醇**(allopurinol)**安全性的最新資訊

Latest safety update on allopurinol

資料來源：中國台灣行政院衛生署
新加坡藥監局
Sources：Department of Health, Executive Yuan, Taiwan, China
Health Sciences Authority, Singapore
http://www.doh.gov.tw/CHT2006/DM/DM2_p01.aspx?class_no=25&now_fod_list_no=10519&level_no=2&doc_no=72789
http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/safety_information/product_safety_alerts/safety_alerts_2009/serious_skin_reactions.html

最近由新加坡藥監局(Health Science Authority)和中國台灣衛生署(Taiwanese Department of Health, China)發佈的藥物安全性訊息指出，漢人所產生的別嘌醇嚴重皮膚不良反應(serious cutaneous adverse reactions, SCAR)與其基因有密切的關係。別嘌醇(a11opurinol)是常用的黃嘌呤氧化酶抑制劑，用於預防和/或治療痛風的高尿酸症、痛風性關節炎、化療後的治療和腎石症(尿酸或重覆的草酸鹽)。眾所周知，別嘌醇可引起如史蒂文生氏強生綜合症(Stevens-Johnson Syndrome, SJS)和毒性表皮溶解症(Toxic Epidermal necrolysis, TEN)等嚴重甚至致死的皮膚反應。據一項有關別嘌醇可引起如史蒂文生氏強生綜合症基因學回顧性研究，人類白血球抗原 HLA-B*5801 (Human Leukocyte Antigen HLA-B*5801)的基因令漢人較易發生 SJS，TEN 和 Allopurinol Hypersensitivity Syndrome (AHS)等症狀。而該基因被證實是別嘌醇引起嚴重皮膚不良反應(SCAR)的基因標誌。雖然在台灣、馬來西亞和菲律賓，別嘌醇引起的嚴重皮膚不良反應是高於日本和歐洲人，然而 7%非洲人、約 2~7%的高加索(白)人、8%的亞洲人 - 當中包括印度人亦帶有這個人類白血球抗原 HLA-B*5801 的基因。基因篩選無疑可識別帶有這人類白血球抗原 HLA-B*5801 基因的人士，但不能代替臨床觀察和監測患者在服用別嘌呤醇產生藥物不良反應早期徵兆。

衛生專業人員應留意與別嘌醇有關的嚴重皮膚反應，亦應在治療高尿酸血症和預防癌症化療引起的高尿酸血症時保持警覺。由於皮疹及皮膚反應等早期症狀可能暗示更嚴重的反應如 SJS 或 TEN，衛生專業人員應教導病人當發覺早期的過敏反應，應即時向醫生求診。

Recent safety releases from the Singaporean Health Science Authority (HSA) and the Taiwanese Department of Health, China described about a strong genetic association of patients with Han-Chinese ancestry in developing allopurinol-induced serious cutaneous adverse reactions (SCAR). Allopurinol, a widely prescribed xanthine oxidase inhibitor, is indicated for the treatment and/or prevention of hyperuricaemia in gout, gouty arthritis, in post-chemotherapeutic therapy and in renal calculi (uric acid or recurrent oxalate). This drug is well-known for causing serious skin reactions such as Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) that leads to significant morbidity and mortality. Results from a retrospective pharmacogenetic study on allopurinol-induced SCAR indicated a strong association of the Human Leukoocyte Antigen ¡ HLA-B*5801 allele with the susceptibility of allopurinol-induced SJS, TEN and allopurinol hypersensitivity syndrome (AHS) in Han-Chinese. HLA-B*5801 allele has been identified as a genetic marker for severe cutaneous adverse reactions (SCAR) caused by allopurinol. Though the incidence rate of allopurinol-induced SCAR in Taiwan, Malaysia, and the Philippines is higher than that of Japan and Europe, it is important to recognize that 7% of African, ~ 2-7% of Caucasian, and 8% of the Asian ¡ Indians can also be the carriers of the HLA-B*5801 allele. Genetic screening may identify the susceptible carrier but this is not a substitute for clinical observation and monitoring of patient for early signs of adverse drug reaction during allopurinol treatment.

Healthcare professionals should be vigilant of the cases of serious skin reactions associated with allopurinol and exercise caution with the use of this drug during treatment of hyperuricaemia and its complications, including its prophylactic use in the prevention of hyperuricaemia associated with cancer treatment. As early signs of rash and skin reactions may be indicative of a more serious reaction such as SJS or TEN, healthcare professionals are advised to educate their patients on early recognition of allergic reactions, immediately seek medical advice.

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