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Reaksi

DRUG SAFETY NEWS

NATIONAL CENTRE FOR ADVERSE DRUG REACTION MONITORING, NPCB

Mission: This publication provides information and recommendations to healthcare professionals to enhance communication of drug safety updates, raise awareness of adverse drug reactions reported, and stimulate additional adverse drug reaction reporting. It is a newsletter published bimonthly by the National Centre for Adverse Drug Reaction Monitoring, National Pharmaceutical Control Bureau (NPCB), Malaysia.

TO REPORT AN ADVERSE DRUG REACTION

Online

1. Visit www.bpfk.gov.my
2. Click on MADRAC (Adverse Drug Reaction)
3. Click on Reporting Online
4. Submit the form once completed.

Mail

1. Fill up the Adverse Drug Reaction form
2. Mail it to :
   National Centre for Adverse Drug Reaction Monitoring,
   Centre for Post Registration of Products, National Pharmaceutical Control Bureau, Ministry of Health,
   PO Box 319, Jalan Sultan,
   46730,Petaling Jaya,
   Selangor

Telephone

03-78835400

Fax

03-79567151

In This Issue:

Ketoconazole: Suspension of Marketing Authorisation in France Due To Risk of Severe Hepatotoxicity

On 8th June 2011, the French health authority, AFSSAPS had announced their decision to suspend the French marketing authorisation of Nizoral® Tablet, an antifungal due to the risk of severe hepatic lesions that are potentially irreversible and life-threatening.

The decision was made following the assessment of cumulative safety data, which reveals a risk of hepatotoxicity, the frequency and severity of which appear to be greater than those of other available azole antifungal agents. However, this regulatory action applies only to the oral formulation of ketoconazole. Topical ketoconazole, with formulations such as cream, shampoos and ovules, are not included given the very low systemic exposure and the lack of cases of liver toxicity.

In Malaysia:

Overall, there are 16 oral products containing ketoconazole registered and since 2001, the National Centre for ADR Monitoring has received 20 reports (38 events) with 7 reports related to hepatic injury.

Advice To healthcare providers:

- A risk and benefit evaluation should be made before oral ketoconazole is used in cases of non-life threatening diseases requiring long treatment periods.
- Liver function on all patients receiving treatment with ketoconazole should be monitored.

Champix® (Varenicline): Potential Risk of Certain Cardiovascular Events in Patients with Cardiovascular Disease

On 16th June 2011, the US FDA reviewed a randomised clinical trial (RCT) of 700 smokers with cardiovascular (CV) disease who were treated with Chantix® (brand name for varenicline in the US) or placebo. In this trial, Chantix® was effective in helping patients quit smoking and remain abstinent from smoking for as long as one year. However, certain events, including heart attack were reported more frequently in patients treated with Chantix® than in patients treated with placebo.

In Malaysia:

Since 2008, the National Centre for ADR Monitoring has received 117 reports related to varenicline, of which 6 reports were CV-related.

Advice to healthcare providers:

- Smoking is an independent and major risk factor for CV disease, and Champix® is effective in helping patients quit smoking.
- Weigh the known benefits of Champix® against the potential risks of its use in smokers with CV disease.
- Counsel patients to seek medical attention if they experience new or worsening symptoms of CV disease while taking Champix®.

Zyvox (Linezolid) & Methylene Blue: Serious Central Nervous System Reactions Possible When Given to Patients Taking Certain Psychiatric Medications

On 26th July 2011, US FDA had announced receiving a few reports of serious central nervous system (CNS) reactions; i.e serotonin toxicity when an antibacterial drug; Linezolid, or a dye used for diagnostic procedure; methylene blue was given to patients receiving serotonergic psychiatric medication.

In Malaysia:

Presently, there are 5 registered products containing linezolid. Methylene blue is not registered in the country and is brought for certain indications through the approval of the Director General of health. No adverse drug reaction pertaining to central nervous system or psychiatric disorder has been reported for both of these drugs.

Advice to healthcare providers:

- Enquire if patients are taking any serotonergic medications before prescribing linezolid and methylene blue.
- These drugs should not be initiated on such population unless in life threatening situations.
- If needed, make sure there is a serotonin drug free period for at least five half-lives of medication before these medications are started.
- Signs and symptoms of serotonin toxicity should be observed on a daily basis.