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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.

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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

Clostridium Difficile - Associated Diarrhoea (CDAD) may be linked to Proton Pump Inhibitors (PPIs)

PPIs are used to treat conditions such as gastro esophageal reflux disease (GERD), stomach and small intestine ulcers, and inflammation of the esophagus.

Clostridium difficile (C. difficile) is a bacterium that can cause diarrhea that does not improve. Symptoms include watery stool, abdominal pain, and fever, and patients may go on to develop more serious intestinal conditions. The disease can also be spread in hospitals.

Although other predisposing factors like advanced age, chronic underlying medical conditions and concomitant broad spectrum antibiotics could increase the risk of CDAD, based on a US Food and Drug Administration (US FDA) review of published papers, the role of PPIs cannot be definitively ruled out and patients who have one or more risks factors may have serious outcomes from CDAD with concomitant PPIs use.

In Malaysia

There are 69 PPIs registered in Malaysia. Since year 2000, there are 14 diarrhoea cases reported to the National Centre for ADR Monitoring. It is believed that such cases are under-reported.

Advice for healthcare providers:

- PPIs should be prescribed at the lowest dose and shortest duration of therapy appropriate to the condition being treated.
- Advise patients to seek immediate care if they experience watery stool that does not go away, abdominal pain, and fever while taking PPIs.
- A diagnosis of CDAD should be considered for any patient who has risk factors for CDAD and who has persistent or severe diarrhoea.
- Any adverse events suspected to be associated with the use of PPIs should be reported to the National Centre for ADR Monitoring.

Association of Domperidone Maleate with Serious Ventricular Arrhythmia and Sudden Cardiac Death

In March 2012, Health Canada informed healthcare professionals that domperidone should be initiated at the lowest possible dose in adults. Recent epidemiological studies have shown that the use of domperidone may be associated with an increased risk of serious ventricular arrhythmias or sudden cardiac death, particularly in patients taking daily doses greater than 30mg and in patients older than 60 years of age.

Health Canada's communication was also based on the results of a population-based case-control study conducted in the Integrated Primary Care Information database in the Netherlands and a nested case-control study performed in the linked administrative databases of Saskatchewan Health.

In Malaysia

There are 16 registered domperidone products in Malaysia. Since year 2005, the National Centre for ADR Monitoring has received 8 reports related to skin disorders, CNS disorders and GI disorders. No report was associated with serious ventricular arrhythmias, sudden cardiac death or other cardiac events.

- The risks of serious ventricular arrhythmias or sudden cardiac death may be higher in patients taking daily doses of more than 30 mg and in patients older than 60 years of age.
- Domperidone should be initiated at the lowest possible dose, which may be adjusted upward with caution to achieve the desired effect as needed.
- In addition, the expected benefit of an increased dose should outweigh the potential risks.
- Patients should be advised to seek prompt medical attention if they experienced signs or symptoms of an abnormal heart rate or rhythm such as syncope, dizziness, palpitations or seizure which occur during treatment with domperidone.
- Domperidone should be avoided in patients who are taking concomitant medication known to cause QT prolongation (such as ketoconazole and erythromycin).
- Any adverse events suspected to be associated with the use of domperidone should be reported to the National Centre for ADR Monitoring.

ADR Reported on Malathion: 2 case reports

The National Centre for Adverse Drug Reactions Monitoring has received 2 reports on Malathion as follows:

1) A 3 year old child developed vomiting, severe abdominal pain and fit-like symptoms 10 minutes after applying a malathion shampoo for head lice infestations. The child was hospitalised for thorough observation. The abdominal pain attacks occurred every 20 to 30 minutes and lasted for 2 days from onset
2) Similarly, another case which was reported in year 2011, relates to a 34 year old man who developed nausea, vomiting and diarrhoea within one hour after using a malathion product for scabies. The malathion product was discontinued and all symptoms resolved.

Editorial comment: Malathion is an organophosphate parasympathomimetic which binds irreversibly to cholinesterase.It is used in various industries and at low doses, malathion can also be used externally in the treatment of head lice and scabies. The WHO Database contains 18 reports of vomiting, 27 reports of nausea, 9 reports of abdominal pain and 10 reports of diarrhoea.

Advice for healthcare providers:

- Counsel patients to recognize the signs and symptoms of adverse reactions for malathion and advise them to seek medical attention promptly if they experience any of the above symptoms.
- Any adverse events suspected to be associated with the use of malathion should be reported to the National Centre for ADR Monitoring.