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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. Print out ADR form available on website and complete it.
2. Mail or fax 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:

Velcade®(Bortezomib): Fatal Cases Due To Erroneous *Intrathecal* Administration

Velcade® (bortezomib) is a cytotoxic agent indicated via intravenous injection as a single agent or in combination with oral melphalan and oral prednisolone for the treatment of patients with multiple myeloma and mantle cell lymphoma. Johnson & Johnson Sdn Bhd in discussion with NPCB issued a Direct Healthcare Professional Communication (DHPC) letter reminding that the correct procedure for administering Velcade is via the **intravenous route**. The dissemination of the DHPC followed the reporting of 3 fatal cases worldwide due to erroneous intrathecal administration of Velcade.

In Malaysia

37 reports on adverse events have been received since its registration in 2005, of which none was related to erroneous administration.

Advice for Healthcare Professionals:

- The only authorised route of administration for Velcade is intravenous injection. Velcade must not be administered by any other route.
- Use **different connectors** for medicinal products to be administered via the intrathecal or intravenous route.
- Administer intrathecal chemotherapy at a **different time** to any other parenteral chemotherapy.
- Clearly **label syringes** with the product name and route of administration and ensure proper procedures are in place to enforce **double reading** of syringe labelling before administration.

Bondronat® (Ibandronic Acid): Association With Anaphylactic Reaction

Bondronat® (Ibandronic acid) is indicated for prevention of skeletal events in patients with breast cancer and bone metastases and treatment of tumour-induced hypercalcaemia with or without metastases. Roche (M) Sdn Bhd in discussion with NPCB issued a Direct Healthcare Professional Communication (DHPC) letter and updated safety information that cases of anaphylactic reaction/shock, including fatal events, have been reported in patients treated with IV ibandronic acid.

In Malaysia

To date there are no reports on anaphylactic shock by ibandronic acid since it was registered in 2006.

Advice for Healthcare Professionals:

- Appropriate medical support and monitoring measures should be readily available when ibandronic acid intravenous injection is administered.
- If anaphylactic or other severe hypersensitivity/ allergic reactions occur, immediately discontinue the infusion/injection and initiate appropriate treatment.
- Any adverse events suspected to be associated with the use of Bondronat must be reported to the National Centre for ADR Monitoring, NPCB.

Case Report: Amiodarone Associated Thyroid Dysfunction

Amiodarone is a potent antiarrhythmic drug that is used to treat tachyarrhythmias. It contains approximately 37% iodine by weight and is structurally similar to thyroxine (T4). Standard maintenance therapy with 200mg amiodarone can provide more than 100 times the daily iodine requirement. The elimination half-life of amiodarone is highly variable, ranging from 50 to 100 days; total body iodine stores remain increased for up to 9 months after discontinuation of the drug. Thyroid abnormalities have been noted in up to 14-18% of patients receiving long term amiodarone therapy.

In Malaysia

Only **2** reports have been received by NPCB since year **1987**. Both cases are reported on 200mg of amiodarone and provided a causality assessment as possible (WHO criteria):

1) A 40 year-old male developed thyrotoxicosis after 3 weeks on amiodarone therapy. He was also on antidiabetic medication.
2) A 72 year-old male, developed hyperthyroidism (onset and other medications unknown).

Postmarketing reports from WHO reveals 2263 cases of hyperthyroidism reported worldwide since year 1975*. Locally, amiodarone induced thyroid dysfunction is believed to be under reported.

*[*The information comes from a variety of sources, and the likelihood that the suspected adverse reaction is drug-related is not the same in all cases and it does not represent the opinion of WHO.]*

Advice for Healthcare Professionals:

- All patients on amiodarone should have their thyroid functions tested at baseline and after 3 months of therapy. Periodic monitoring is recommended if TSH levels are abnormal or clinical suspicion of thyroid dysfunction exists.
- If a patient develops hyperthyroidism due to amiodarone, it should be withheld (depending on the severity of arrhythmia or whether an alternative is available) or been treated with antithyroid medication.
- Any adverse events suspected to be associated with the use of amiodarone must be reported to the National Centre for ADR Monitoring, NPCB.