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Reaksi

DRUG SAFETY NEWS

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.

This is a bimonthly publication by the Drug Safety Monitoring Centre, National Pharmaceutical Control Bureau (NPCB), Malaysia.

In This Issue:

TO REPORT AN ADVERSE DRUG REACTION

Scan, Fill, Submit

Online

1. Visit www.bpfk.gov.my.
2. Click on ADR Reporting and Product Complaints.
3. Click to report as a healthcare professional via online or hardcopy.
4. Submit the form once completed.

Mail

1. Print out the ADR form available our website and complete it.
2. Mail or fax to:
   The Drug Safety Monitoring Centre, Centre for Post Registration of Products, National Pharmaceutical Control Bureau, Ministry of Health, PO Box 319, Jalan Sultan, 46730 Petaling Jaya, Selangor.

Telephone

03-7883 5400
(ext. 5542/ 8461/ 8463)

Fax

03-7956 7151

Montelukast: Reminder on the Neuropsychiatric Risks

Healthcare professionals are reminded to keep in mind the risk of montelukast causing neuropsychiatric adverse reactions, such as aggressive behavior, anxiety, depression, hallucination and suicidal ideation. These known side effects of the drug are mentioned in the package insert under "Precautions", with healthcare professionals being advised to discuss these adverse events with patients and/or caregivers and instruct the patients and/or caregivers to report if they experience any of these reactions.

Montelukast is a leukotriene receptor antagonist first registered in Malaysia in 1999 for the prophylaxis and chronic treatment of asthma, as well as to relieve symptoms of seasonal allergic rhinitis.

Since the year 2000, 97 ADR reports on montelukast have been received by the NPCB involving 159 reactions. The most common reactions reported were rash (15 reports), oedema (12), and vomiting (7).

Twenty-four of the reports received (25%) involved psychiatric disorders, including difficulty sleeping (9), aggressiveness (6), hallucination (4), confusional state (2), irritability (2) and mood swings (2). More than half the reports (13 cases) involved children aged between 2 to 10 years. The onset generally ranged between a few hours to 10 days.

In 2009, the United States Food and Drug Administration (US FDA) had conducted a safety review of the leukotriene receptor inhibitors montelukast, zafirlukast, zileuton, and concluded that although the potential for psychiatric adverse effects was very small, healthcare providers must be aware and monitor patients for them. Both zafirlukast and zileuton are not registered in Malaysia.

In April 2013, the Therapeutic Goods Administration (TGA) of Australia reported 58 neuropsychiatric adverse events over the last 13 years involving montelukast used in children and adolescents. The TGA reminded healthcare professionals and caregivers of children to be watchful for such adverse effects, especially when treatment is first started or dosage is increased.

Advice to healthcare providers:

- Inform patients and/or their caregivers on the risk of neuropsychiatric adverse effects with montelukast treatment.
- Monitor patients for these effects and consider the risks and benefits of the continuing the medication if a patient develops these reactions.
- Kindly report any adverse events suspected to be associated with the use of montelukast to the Drug Safety Monitoring Centre, NPCB.

Roflumilast: Risk of Suicidal Behaviour

Roflumilast is a phosphodiesterase-type-4 (PDE4) inhibitor indicated for maintenance treatment of severe chronic obstructive pulmonary disease (COPD) associated with chronic bronchitis in adult patients with a history of frequent exacerbations as add on to bronchodilator treatment.

The Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom, recently alerted users of this drug on the increased risk of psychiatric adverse effects, which have been reported in clinical trials as well as postmarketing data. Clinical trial results demonstrated an increased risk of insomnia, anxiety, nervousness and depression, with rare cases of suicidal ideation and behavior. Postmarketing data reviewed recently also revealed cases of suicidal behavior. Other possible side effects that may be serious and should be monitored are diarrhoea and weight loss.

Since its registration in 2011, NPCB has received 6 adverse drug reaction reports related to roflumilast which were assigned the causality C3 (possibly-related). These involved 9 reactions with only one psychiatric disorder reported, namely drowsiness. The other reactions reported were diarrhoea (3), headache, vomiting, bodily discomfort, dyspepsia, and gastric irritation (1 each).

Advice to healthcare providers:

- The risks and benefits of using roflumilast should be carefully assessed in patients who have suffered from psychiatric symptoms or are concomitantly taking other medicines which may cause psychiatric symptoms.
- Counselling must be given to patients and/or caregivers to report any change in behavior or mood, including suicidal thoughts and self-harm.
- If patients experience new or worsening psychiatric symptoms or have suicidal behavior, roflumilast treatment should be stopped.
- Any adverse event suspected to be associated with the use of roflumilast should be reported to the Drug Safety Monitoring Centre, NPCB to ensure local postmarketing data is captured for this new product.