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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

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), Ministry of Health, Malaysia.

In This Issue:

Avastin® (bevacizumab): Severe Infectious Endophthalmitis Leading to Blindness Following Unapproved Intravitreal Injection

In November 2011, Roche (M) distributed a Dear Healthcare Professional Communication (DHPC) to inform about cases of severe infectious endophthalmitis leading to blindness or near blindness following use of compounded Avastin® for unapproved intravitreal injection. These ophthalmologic adverse events (e.g. acute ocular inflammation, endophthalmitis, vitritis, uveitis) had occurred both as individual events and in clusters. While a causal relationship has not been established, it is believed that the events resulted from the repackaging of Avastin® without proper aseptic technique.

Avastin® is a recombinant humanised monoclonal antibody that is directed against the vascular endothelial growth factor (VEGF). It is approved for the intravenous treatment of metastatic colorectal cancer, metastatic breast cancer, advanced, metastatic or recurrent non small cell lung cancer, advanced and/or metastatic renal cell cancer, as well as glioblastoma. Please refer to the package insert for complete indications.

In Malaysia:

There are 3 registered bevacizumab products in Malaysia, all under the brand name Avastin®. Since the first registration in 2005, 12 reports have been received, with 1 report where Avastin® was used for the treatment of macular degeneration of retina. The patient suffered from eye infection after 1 time use and the outcome was not known.

Advice to healthcare providers:

- Bevacizumab is not formulated for intravitreal use.
- The practice of repacking bevacizumab into multiple aliquots for intravitreal use may be associated with contamination.
- Any adverse events suspected to be associated with the use of bevacizumab should be reported to the National Centre for ADR Monitoring.

Saphris® (asenapine maleate): Potential Risk of Serious Allergic Reactions

Serious allergic reactions have been reported with the use of Saphris®, an atypical antipsychotic. The Type 1 hypersensitivity reactions may include anaphylaxis, angioedema, hypotension, tachycardia, swollen tongue, dyspnoea, wheezing or rash. In the US, 52 reports of such reactions were received. In several cases, these reactions occurred after the first dose.

Saphris® is approved in Malaysia for the treatment of schizophrenia, and as mono- or adjunctive therapy for the acute treatment of manic or mixed episodes associated with bipolar 1 disorder.

In Malaysia:

There are 2 registered asenapine products in Malaysia, i.e. Saphris Sublingual Tablet 5mg and 10mg. No ADR report has been received locally since their registration in 2011.

Advice to healthcare providers:

- Asenapine is contraindicated in patients with a known hypersensitivity to the product.
- Educate patients to recognise the signs and symptoms of a serious allergic reaction and advise them to seek medical attention if they experience any of these symptoms.
- Any adverse events suspected to be associated with the use of asenapine should be reported to the National Centre for ADR Monitoring.

Xigris® [drotrecogin alfa (activated)]: Voluntary Market Withdrawal due to Failure to Show Survival Benefit

On October 25, 2011, Eli Lilly & Co. announced a worldwide voluntary market withdrawal of Xigris®, an antithrombotic agent. This decision was taken following a recently completed clinical trial (PROWESS-SHOCK), which showed that Xigris® failed to meet the primary endpoint of a statistically significant reduction in 28-day all-cause mortality in patients with septic shock.

Xigris® is a recombinant human activated protein C, indicated for the treatment of adult patients with severe sepsis with multiple organ failure when added to best standard care.

In Malaysia:

There were 2 registered drotrecogin alfa products in Malaysia, i.e. Xigris® 5mg and 20mg. All Xigris® products have been withdrawn from the market and destructed appropriately following this decision.