



SFDA SAFETY COMMUNICATION

18 December 2011

Saudi Food and Drug Authority (SFDA) PRESS RELEASE – Safety of AVASTIN® (bevacizumab)

The Saudi Food and Drug Authority (SFDA) would like to provide healthcare professionals (HCPs) with an important safety information concerns the intravitreal use of AVASTIN®:

- Recently, Roche became aware of a cluster of Streptococcal endophthalmitis involving 12 patients injected with AVASTIN® within four days in the United States. The reports of infection appear to be the result of contamination following compounding AVASTIN®, although the exact cause of the infection is under investigation. Most of these patients have reported blindness or near blindness in the injected eye as a result of this infection.
- Following the intravitreal use of AVASTIN®, other clusters of acute ocular inflammation and endophthalmitis have recently been reported in the U.S.
- Inflammatory events, such as vitritis, uveitis, and sterile endophthalmitis, have previously been reported both as individual events and in clusters, (Following the compounding of a single vial in a large number of syringes). Some of these events have led to blindness.

AVASTIN® IS NOT APPROVED FOR ANY INDICATION IN SAUDI ARABIA, INCLUDING OPHTHALMIC APPLICATIONS.

AVASTIN® is packaged into single-use sterile preservative free vials for intravenous use in the oncology setting; the practice of repackaging single-use AVASTIN® vials for intravitreal use into multiple aliquots may be associated with the contamination of the product.

The SFDA would like to notify HCPs that the manufacturer of the product will issue a Dear Health Care Professional Letter (DHCPL) to inform them about this safety concern.

Report Adverse Drug Reactions (ADRs) to the Saudi FDA

The SFDA urges both healthcare professionals and patients to report ADRs resulted from using such a medication and other medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance and Drug Safety Center (NPC)
Saudi Food and Drug Authority-Drug sector
3292 Northern Ring Road
Al Nafal District
Riyadh 13312 – 6288
Kingdom of Saudi Arabia
Tel: 8002490000 Or 012759222 ext. 2334, 2317, 2353, 2354, 2356
Fax: 012057662
Email: NPC.Drug@sfd.gov.sa
Website: www.sfd.gov.sa/NPC