



Subject: Direct Healthcare Professional Communication on Cases of Necrotizing Fasciitis Reported with AVASTIN®

7 April 2013

Dear Healthcare Provider,

F. Hoffmann-La Roche Ltd. would like to inform you of the following safety information regarding the use of AVASTIN® (bevacizumab):

Summary

- Necrotizing fasciitis, including fatal cases, have been reported in patients receiving AVASTIN in clinical trials and in the post-marketing setting.
- It is recommended that AVASTIN is discontinued and appropriate therapy initiated promptly upon diagnosis of necrotizing fasciitis.

Further information on the safety concern

Necrotizing fasciitis is a rare but life-threatening infection of the soft tissue, characterized by rapidly spreading necrosis of superficial fascia and subcutaneous tissue. Immuno-compromised patients are at a higher risk of developing necrotizing fasciitis.

The reported cases of necrotizing fasciitis in Roche clinical trials and global safety database occurred in patients with several types of cancer. Regarding associated medical conditions; the majority of the patients had gastrointestinal perforation, fistula formation or wound healing complications preceding the development of necrotizing fasciitis. Some of these patients died due to complications of necrotizing fasciitis.



The information in this letter has been agreed with the Saudi Food and Drug Authority (SFDA).

Call for reporting

Health care professionals should report any serious adverse events suspected to be associated with the use of AVASTIN according to national reporting requirements.

Should you have any questions regarding the use of AVASTIN, please feel free to contact us under the below address:

Company contact point


Hoffmann-La Roche
Saudi Import Company
Najoud Centre, Gate A, 1st Floor.
Prince: Mohamed Bin Abdulaziz St.
Phone: 009662 2847190
Mobile: 00966561968563
Email: hazem.dajani@roche.com

Alternatively, report this information to:


The National Pharmacovigilance & Drug safety Centre (NPC)
Saudi Food and Drug Authority (SFDA)
Fax: +966-1-2057662
Email: Npc.drug@sfda.gov.sa

Yours Sincerely,

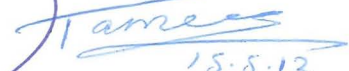
Hazem Al-Dajani
Local Safety Responsible


15/5/2013

Naser Al-Rajhi
Scientific office director


18 May 2013

Tamer Elmahallawy
Medical Director


15.5.13