GlaxoSmithKline
Scientific Office

جلاكسو سميث كلاين
المكتب العلمي

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Title: ARZERRA® (ofatumumab) – Safety update on a fatal infusion reaction reported in a patient with Chronic Lymphocytic Leukemia (CLL) who was treated with intravenous ofatumumab

Dear Healthcare Professional:

ARZERRA® is indicated for the treatment of chronic lymphocytic leukaemia (CLL) in patients who are refractory to fludarabine and Alemtuzumab. GSK has received a report of death following an infusion reaction which occurred during administration of the first dose of ofatumumab in a 71-year old male with CLL and no known history of cardiac disease. GSK is informing healthcare providers who may utilize ofatumumab of this event.

Key Message

- GSK has updated or is in the process of updating the Warnings and Precautions statement on infusion reactions associated with intravenous administration of ofatumumab to note that reactions can be fatal.
- GSK reminds healthcare professionals:
    - Despite premedication, infusion reactions may still occur. In cases of severe infusion reaction, the infusion of ofatumumab must be interrupted immediately and symptomatic treatment instituted.
    - Ofatumumab should be administered under the supervision of a physician experienced in the use of cancer therapy
    - Ofatumumab should be administered in an environment where facilities to adequately monitor and treat infusion reactions are available
    - Follow premedication protocol as defined in the label including that patients should receive premedication agents 30 minutes to 2 hours prior to each infusion
        - Oral paracetamol (acetaminophen) 1000 mg (or equivalent), plus
        - Oral or intravenous antihistamine (diphenhydramine 50 mg or cetirizine 10 mg or equivalent), plus
        - Intravenous corticosteroid (prednisolone 100 mg or equivalent).

Action Being Taken by GlaxoSmithKline

GSK has updated the internal safety information and the label for ARZERRA® to reflect the potential for fatal infusion reactions. This updated information will be reflected in the local prescribing information in all countries in which ARZERRA® is licensed.

A Dear Investigator Letter (DIL) is being issued to investigators involved in GSK-sponsored clinical trials. In addition, all investigators who are themselves the sponsors of an ofatumumab study supported by GSK have been provided with this safety information.

Revised Labeling

Local prescribing information to be updated to reflect the new safety update after taking the approval from the Saudi Food and Drug Authority.

The letter is sent in agreement with the Saudi Food and Drug Authority

Call for reporting

GlaxoSmithKline will continue to monitor the safety of ARZERRA® (ofatumumab) and update SFDA of any serious adverse event for evaluation. You can assist us in monitoring the safety of ARZERRA® (ofatumumab) by reporting adverse reactions to fax: +966 12 6536660 or by email to GlaxoSmithKline safety email: faisal.m.shujrah@gsk.com Or to the National Pharmacovigilance and Drug Safety Center at Fax: +966 11 2057662 or by email to: npc.drug@sfda.gov.sa

If you have any question about the new information, please contact GSK medical information department at GlaxoSmithKline Saudi Arabia by phone: +966 12 6536666 or fax: +966 12 6536660.

Best regards

P.P.

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