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Direct Healthcare Professional Communication on the association of BENLYSTA® (belimumab) with hypersensitivity and infusion reactions

License Number: EU/1/11/700/001(120 mg IV) & EU/1/11/700/002 (400 mg IV)

05th March 2012

Dear Healthcare Professional:

Summary

- Administration of Benlysta may result in severe or life-threatening hypersensitivity and infusion reactions.
- Delay in the onset of acute hypersensitivity reactions has been observed.
- Due to the risk for late onset hypersensitivity reactions, patients should remain under clinical supervision for a prolonged period of time (for several hours) following at least the first 2 infusions.
- The Summary of Product Characteristics and Package Leaflet are being revised to include information on this safety risk.

The information contained in this letter has been endorsed by the European Medicines Agency and national Competent Authorities.

Further information on the safety concern

At the time of approval of Benlysta, a higher incidence of hypersensitivity reactions compared to placebo was reported and information and warnings were included in the product information. Recently, a number of post-marketing reports concerning serious acute hypersensitivity reactions, some of which appear to have been delayed beyond the typical 1-2 hours seen in previous clinical trials, have been identified. Patients have been reported to develop acute symptoms several hours after the infusion has been given, for example in the evening on the day the drug was administered. One patient died after she developed dyspnea, respiratory distress, hypoxia and angioedema following the second infusion of belimumab. The onset of symptoms was suspected to begin approximately 4 hours after the end of belimumab infusion. The patient had a history of multiple drug allergies.

Further recommendations to healthcare professionals

- Benlysta treatment should be initiated and supervised by a qualified physician experienced in the diagnosis and treatment of SLE.
- Benlysta should be administered in an environment where resources for managing such reactions are immediately available

- Delay in the onset of acute hypersensitivity reactions has been observed. To reduce risk, patients should remain under clinical supervision for a prolonged period of time (for several hours) following at least the first 2 infusions.
- Recurrence of clinically significant reactions after initial appropriate treatment of symptoms has been observed. The health care provider should inform the patient of the potential risk, the seriousness of such reactions, and the importance of immediately seeking medical attention.
- Premedication including an antihistamine, with or without an antipyretic, may be administered before the infusion. However, there is insufficient knowledge to determine whether premedication could diminish the frequency or severity of infusion reactions to Benlysta.
- The Package Leaflet is currently being revised; once the updated version is available it should be provided to the patient each time Benlysta is administered.

Call for reporting

GlaxoSmithKline encourage healthcare professionals to continue to report adverse reactions to either the Irish Medicines Board or GlaxoSmithKline. The Irish Medicines Board can be contacted at (01) 676 4971 or online at www.imb.ie. GlaxoSmithKline can be contacted at (01) 4955000 or e-mail Ireland.drugsurveillance@gsk.com.

Communication Information

Should you have any questions or require additional information please contact us on (01) 4955000.

Yours sincerely,

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