



荷商葛蘭素史克藥廠股份有限公司台灣分公司 書函

機關地址：10018 台北市忠孝西路一段 66 號 24 樓  
聯絡人及電話：(02)23818866  
電子郵件信箱：frederick.x.lee@gsk.com

受文者：裕利股份有限公司/吉程股份有限公司/裕翔  
藥品股份有限公司

副 本：衛生福利部食品藥物管理署

發文日期：中華民國 108 年 03 月 05 日

發文字號：GSK108028 號

附 件：奔麗生凍晶注射劑(Benlysta Powder for Solution for Infusion)藥  
品安全性訊息：Dear Healthcare Provider Letter

主 旨：通知本公司藥品衛署菌疫輸字第000935號「奔麗生凍晶注射劑(Benlysta Powder for Solution for Infusion)」藥品安全性訊息，並請協助轉知近六個月各使用之醫療單位、藥局、經銷商、中華民國藥師公會全國聯合會、社團法人台灣臨床藥學會及台灣年輕藥師協會。

說 明：

- 一、一為期五十二周之大型雙盲隨機臨床觀察研究顯示，相較於對照組，使用奔麗生凍晶注射劑者出現自殺意念或自傷傾向的案例較多(0.7% [n= 15] vs. 0.2% [n=5])。此為尚待統計驗證之初步結果。(詳如附件一)
- 二、GSK將著手更新產品仿單以確保產品安全訊息無慮。
- 三、敬請 貴單位協助轉知該產品之藥品安全性事宜，懇請繼續給予本公司支持為禱。

荷商葛蘭素史克藥廠股份有限公司台灣分公司

負責人：那 睿 安



第 1 / 1 頁

GlaxoSmithKline Far East B.V. Taiwan Branch

24F, No. 66, Sec 1, Zhong Xiao W. Rd., Taipei 100, Taiwan  
Tel: 886-2-23818866 Fax: 886-2-23120838

## GLAXOSMITHKLINE SAFETY ADVISORY

### Summary of subjects reporting depression or suicidality SAEs\* (As Treated Population)

	Number (%) of Subjects	
	Placebo (N=2001)	Belimumab IV 10 mg/kg (N=2002)
Number of subjects reporting depression SAE	1 (<0.1%)	7 (0.3%)
Number of subjects reporting suicidal ideation or behavior or self-injury SAE	5 (0.2%)	15 (0.7%)

\*as per study investigator report

### Summary of Subjects with C-SSRS# Suicidal Ideation or Behavior during Study Period (As Treated Population)

	Number (%) of Subjects	
	Placebo (N=1988)	Belimumab IV 10mg/kg (N=1974)
Number of subjects with at least one on-study C-SSRS assessment		
Number of subjects reporting Any Suicidal Ideation or Behavior event	39 (2.0%)	48 (2.4%)

Note: Percentages are based on the number of subjects with at least one on-study C-SSRS assessment.  
# as per C-SSRS assessment

### Further Information

Reporting Adverse Events: If you become aware of an adverse event involving Benlysta please contact:

#### Contact(s) for reporting Adverse events:

Phone: 02-23126836

e-mail: [oax40892@gsk.com](mailto:oax40892@gsk.com)

#### Contact(s) for Further Information/Questions:

e-mail: [tw.medinfo@gsk.com](mailto:tw.medinfo@gsk.com)

---

Chris Shih, MD  
Medical Director of GSK Taiwan

## GLAXOSMITHKLINE SAFETY ADVISORY

### References

Chi Chiu Mok, Kar Li Chan, Eric Fuk Chi Cheung, Paul Siu Fai Yip; Suicidal ideation in patients with systemic lupus erythematosus: incidence and risk factors, *Rheumatology*, Volume 53, Issue 4, 1 April 2014, Pages 714–721.

Figueiredo-Braga M, Cornaby C, Cortez A, Bernardes M, Terroso G, Figueiredo M, et al. Depression and anxiety in systemic lupus erythematosus: the crosstalk between immunological, clinical, and psychosocial factors. *Medicine*. 2018;97(28):e11376.

Karassa, F. B., Magliano, M., & Isenberg, D. A. (2003). Suicide attempts in patients with systemic lupus erythematosus. *Annals of the rheumatic diseases*, 62(1), 58-60.

Posner et al, *Am J Psychiatry*. 2011 Dec; 168(12): 1266–1277

Tisseverasinghe, A., Peschken, C. & Hitchon, C. Anxiety and Mood Disorders in Systemic Lupus Erythematosus: Current Insights and Future Directions. *Curr Rheumatol Rep* (2018) 20: 85.

Zhang L, Fu T, Yin R, Zhang Q, Shen B. Prevalence of depression and anxiety in systemic lupus erythematosus: a systematic review and meta-analysis. *BMC Psychiatry*. 2017; 17:70.



