

檔 號：
保存年限：

嬌生股份有限公司 函



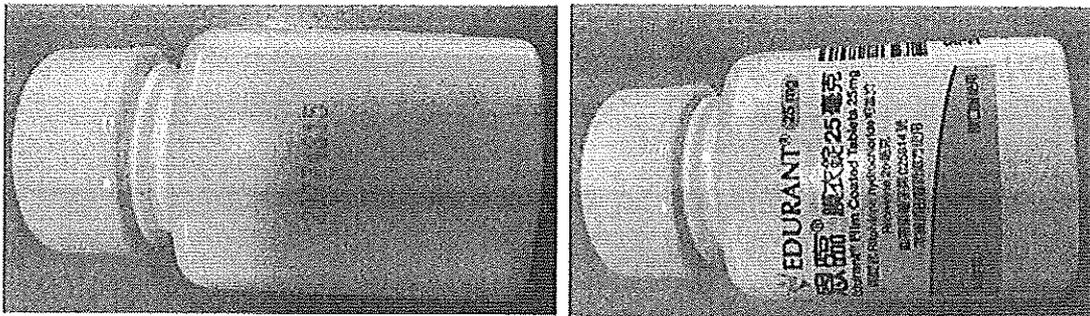
公司地址：台北市中山區民生東路三段2號10樓及11樓
傳 真：(02) 2593-9100
電 話：(02) 2593-9888
聯絡人及電話：楊子昀 02-25939280

105台北市松山區南京東路四段126號
受文者：裕利股份有限公司
發文日期：中華民國110年8月25日
發文字號：(一一〇)台嬌字第0161號

主旨：說明本公司藥品「恩臨®膜衣錠 25 毫克 Edurant® Film Coated Tablets 25mg (衛署藥輸字第 025814 號)」藥品(批號: KJL5S00)之瓶身印有內部辨識碼，並不影響本產品之療效、安全及品質。詳如說明段。

說明：

一、本公司藥品「恩臨®膜衣錠 25 毫克 Edurant® Film Coated Tablets 25mg (衛署藥輸字第 025814 號)」(批號: KJL5S00)包裝完全符合 GMP 要求，唯此批號瓶標並未黏貼於印有內部識別碼那面瓶身上(詳見下列產品圖片)。



二、經下述原廠的評估報告(如附件)可知，此批號之品質並不因其瓶標未黏貼於印有內部識別碼那面瓶身上而有影響：

- 瓶標上印刷的可變數據(批號及效期)清晰可讀
- 直接包材跟設計稿相符
- 並未收到關於此類「外觀缺陷」的訴怨
- 並無特殊法規要求須遮蓋瓶身上的內部識別碼，因此排除法規遵從性的影響
- 並無品質或法規要求使得此瓶是不能被接受的
- 根據包裝過程，不論瓶標黏貼於瓶身的哪一面，相關設備皆能正確的黏貼標籤並能驗證打印的可變數據
- 此類「外觀缺陷」並不影響產品之療效、安全及品質
- 所有品質規格皆符合

- 三、 因此，此批號(KJL5S00)產品之瓶身印有內部辨識碼，並不影響產品療效、安全及品質。預計於9月後將陸續發貨，特此通知貴院。懇請貴院持續支持與愛護，無任感荷。
- 四、 另原廠已將此事件成案(案號：TW#1952304)，以改善貼標過程，避免未來此情形再度發生。若有造成貴院與病患任何不便，敬請見諒，並請繼續支持本公司為禱。

嬌生股份有限公司
負責人：

負責人田中美由紀

To Whom it May concern

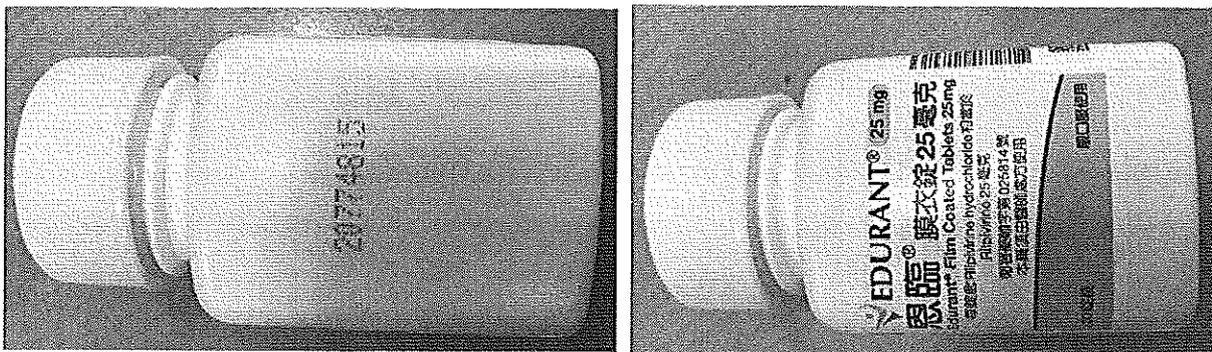
Product name: EDURANT 25MG 30 FC.TABL.TAIW.

Batch name: KJL5S00

Product code: 413241

We, Janssen Cilag Latina S.p.A, hereby certify that the information reported in this statement is authentic and accurate.

The batch KJL5S00, code 413241, EDURANT 25MG 30 FC.TABL.TAIW. has been packaged in full compliance with GMP requirements. The bottle labels are applied without overlapping the internal identifier number printed on the bottle. (For detail see figures below).



A record on Trackwise System (TW#1952304 “Internal identifier number not completely covered by Label bottle for batch KJL5S00, code 413241, EDURANT 25MG 30 FC.TABL.TAIW”) was opened in order to improve the labeling process to avoid future occurrences.

The batch quality has been assessed as following:

- the variable data (batch and expiry date) printed on the label are clearly legible;
- the primary packaging materials and artwork are compliant;
- no market complaints were received for this kind of “cosmetic defects”;
- the regulatory impact for this “cosmetic defects” is excluded since there is not a specific requirement to cover the internal identified number on the bottle;
- there are no quality or regulatory requirements for which this bottle could not be acceptable;
- according to packaging process the equipment is able to correctly apply the label and verify the variable data printed regardless the bottle side on which the label is applied;
- there is no efficacy nor patient safety and product quality impact for the cosmetic defect object of this statement;
- all quality specifications are met.

Therefore, quality impact on the product is excluded.

Date and signature

By signing the present QA MEMO the affiliate accept the batch object of this statement for commercialization purpose.

Date and Signature: