



Advancing Human Health

17 March 2016

**IMPORTANT INFORMATION: DAUNOXOME® (daunorubicin citrate liposome injection)
NDC# 10885-001-01**

NO LONGER AVAILABLE IN U.S. AFTER APRIL 16 2016

Dear DaunoXome® Customer:

Galen US Inc regrets to inform you that DaunoXome® (daunorubicin citrate liposome injection) will no longer be available in the U.S. after April 16, 2016. April 16, 2016 is the date of expiration of the last approved manufactured lot of product and there is no FDA-approved manufacturer available to make additional product. This unfortunate situation has developed as the existing DaunoXome® manufacturer notified Galen some time ago that their ability to manufacture the product was coming to an end. Galen met directly with FDA and corresponded with the agency on multiple occasions to develop a plan to qualify a new manufacturer for DaunoXome®. While Galen would like to continue to support DaunoXome® in the US, the financial investment necessary to meet the FDA manufacturing technology transfer requirements is simply beyond our financial capabilities.

Galen continues to correspond with FDA regarding an importation or “named patient” program for DaunoXome® after April 16, 2016. At this point it is unlikely such a program will be offered but Galen will provide definitive guidance on this topic in the coming weeks. At a minimum Galen will make known the availability of DaunoXome® in other parts of the world in our next communication.

Galen US will be sending out additional notifications in the coming weeks to remind our customers of the pending discontinuation and to ensure no patients are scheduled for therapy beyond the expiration date.

We apologize sincerely for any inconvenience this decision may cause your institution or your patients. It is important to note Galen US has not made a profit on DaunoXome® since acquisition of the product in 2012, but we remained committed to the patients who benefitted from the product. I would like to personally assure you the decision to withdraw was not made lightly. Should you have any questions please contact the individuals noted below.

Sincerely

Andrew D. Shales
General Manager
Galen US Inc



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