



J-C Health Care Ltd.

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September 4, 2011

Potential supply interruption for DOXIL (pegylated liposomal doxorubicin) 20 mg and 50 mg vials for injection

Dear Health Care Provider:

We are writing to inform you about an interruption of supply for DOXIL (pegylated liposomal doxorubicin) 20 mg and 50 mg vials for injection that is likely to result in shortages to patients in Israel over the next few months. The very limited availability of DOXIL is leading us to implement a strict patient allocation programme. However, even with the implementation of such an allocation programme there is a very high probability of a complete stock out situation in the near future, impacting both new patients as well as patients currently on DOXIL.

We advise that no new patients start DOXIL therapy until an adequate supply becomes available, unless these patients have no other treatment option remaining. In addition we advise the following:

- Priority should be given to patients already being treated with DOXIL for whom there is no treatment alternative remaining
- We respectfully request that you do not place orders which exceed these restrictions
- Patients who have already received DOXIL, or will receive available DOXIL stock, should be reassured that this shortage in supply is not due to any concerns over the safety or quality of the product
- Please note that non-liposomal and non-pegylated forms of doxorubicin are not bioequivalent to DOXIL
- Non-anthracycline alternatives may be considered

Further information on the interruption in supply

The manufacturer of DOXIL has experienced production difficulties over the past several months which have caused the current short supply situation. The manufacturer is in the process of resuming operations; however, we do expect supply constraints and we anticipate that patient level shortages may begin within the next weeks in Israel

Every effort is being taken to ensure that DOXIL will remain available to patients who need treatment through active management of the available inventory.



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A Patient Allocation Programme will be rolled out in Israel within the next days which will give priority to patients currently receiving treatment with DOXIL and those patients who have no other treatment options remaining. This programme will assess patients on an individual basis and dispatch stock for their treatment, to restrict treatment disruption to the least number of patients and for the shortest possible time period.

We are also working with the product manufacturer to resume their operations and will prioritise packaging and release of any product made available to us. Based on our current knowledge a very limited amount of stock may be made available to us in November 2011, however, this will be insufficient to meet demand. Even with this additional stock patient allocation programmes will remain in place.

Treatment alternatives—advice for healthcare professionals

- Treatment decisions should be made on an individual patient basis after thorough discussion of the options between the patient and treating physician
- Priority should be given to patients already being treated with DOXIL for whom there is no treatment alternative remaining
- Non-liposomal and non-pegylated forms of doxorubicin are not bioequivalent to DOXIL. Therefore, these alternatives should only be used where the benefits are considered to outweigh the risks for individual patients
- Non-anthracycline alternatives may be considered where the benefits are considered to outweigh the risks for individual patients

We deeply apologise for this unfortunate situation. We will continue to do everything possible to minimize the impact of this supply shortage and assure you that actions are being undertaken to avoid future shortages. We will keep you informed as new information becomes available and the situation changes.

If you have further questions, please do not hesitate to contact Sharon Asheri 0544307178 or Meir Kaplanski 0544307125

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