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janssen
PHARMACEUTICAL COMPANIES
OF Johnson&Johnson

The reintroduction of CAELYX® (pegylated liposomal doxorubicin)

20 mg (2mg/ml) vials for injection

Dear healthcare provider,

Janssen Cilag International NV would like to inform you of the following:

Summary

- We had previously communicated to you about limited availability of CAELYX® due to production difficulties at the product manufacturing site (Ben Venue Laboratories, BVL). We would like to inform you that the CHMP have approved the supply of CAELYX® 20 mg (2mg/ml) vials for injection which involves formulating CAELYX® at BVL, and then transferring it to another manufacturer (DSM) for sterile filtration and filling/packaging.
- It may take several months to build up an inventory of CAELYX® to fulfil the needs of the global demand. It is estimated that a sustainable global commercial supply will be reached by mid 2013. As a temporary measure, we will be introducing the 'CAELYX® Managed Access' programme; an ordering system intended to help manage appropriate allocation of available stock in the EU to patients.
- It is recommended that HCPs prioritise patients who are currently on CAELYX® treatment via the Patient Allocation Programme (PAP) and those for whom no satisfactory alternative treatment is available.
  Due to the limited availability we cannot guarantee each request will be met as it will depend on the global demand. However, the CMA will take into account the full duration of treatment requested for a particular patient, to ensure any patient who commences CAELYX® will receive their full course of treatment.

This information is being communicated to you in agreement with the European Medicines Agency.

CAELYX® Managed Access Programme

The CAELYX® Managed Access (CMA) programme has been put in place to ensure *transparent, consistent and equitable* allocation of CAELYX® to eligible patients within the EU. The CMA programme is a web-based ordering and reservation system that provides feedback on the current availability of CAELYX® so as to help ensure that every patient who starts treatment with CAELYX® will be able to complete a full course of treatment.

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Both the immediate and full treatment requirements will be requested upon receipt of the CAELYX® order from the hospital pharmacist. Janssen Ireland will then place the order via the CMA website. The system checks local stock status and informs Janssen immediately on availability of the CAELYX® supply, for both immediate and projected use. The projected supply of CAELYX® will be reserved for the patient's exclusive use. Janssen will then relay this information to the hospital pharmacist and the order will be processed as a normal hospital order.

Once there is a sustainable commercial supply of CAELYX®, the CMA programme will be terminated.

Further information

- Please find enclosed the process flow diagram for both initial patient registration and re-supply along with both the initial order form and the resupply form.
- www.ema.europa.eu
- caelyxmanagedaccess.com

Company contact point

If you have further questions, please do not hesitate to contact Bláithín Liston, Snr Product Manager, Oncology on 087-9813911, or Kathy Mulligan, Marketing Assistant on 01-6202312.

Yours sincerely,

Julie Lynch

Acting Head of Medical Affairs