29 October 2012
EMA/664564/2012
EMEA/H/C/089/II/0065/G

The recommendations in this document were valid during the supply shortage of Caelyx which was resolved in April 2013. For the updated recommendations see here.

Questions and answers on updated recommendations on the use of Caelyx (doxorubicin hydrochloride)

The European Medicines Agency has updated its recommendations on the use of Caelyx that were issued last year following a shortage of the medicine due to shortcomings in quality assurance identified at the manufacturing site, Ben Venue Laboratories. The Agency's Committee for Medicinal Products for Human Use (CHMP) has agreed to the transfer of the sterile operation for Caelyx to a new manufacturing site and the supply situation of Caelyx is expected to improve. The CHMP no longer considers it necessary to restrict the use of Caelyx to existing patients. It recommends that Caelyx may also be used to start treatment. However, priority should be given to existing patients and new patients for whom no alternative treatment is available.

What is Caelyx?

Caelyx is an anticancer medicine that contains the active substance doxorubicin hydrochloride. It is used in the treatment of the following cancers: metastatic breast cancer, advanced cancer of the ovary, Kaposi's sarcoma (a cancer of the blood vessels) in patients with acquired immune deficiency syndrome (AIDS), and multiple myeloma (a cancer of the cells in the bone marrow).

What were the previous recommendations for Caelyx[1]?

On 22 November 2011 the CHMP issued recommendations that no new patients should be started on Caelyx. This followed an inspection of Ben Venue Laboratories, where a number of sterile medicines including Caelyx were manufactured, which highlighted several problems in quality assurance of the sterilisation process of these medicines. As Ben Venue was the only manufacturing site for Caelyx and all manufacture and distribution of medicines ceased after the inspection, a shortage in the supply of Caelyx followed. The CHMP recommended that Caelyx is an essential medicine for patients who have already started treatment with it and existing Caelyx stocks should therefore be used to complete treatment that had been initiated.

[1] http://www.ema.europa.eu/docs/en_GB/document_library/Medicine_QA/2011/11/WC500117926.pdf

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A review[2] of Caelyx and other medicines manufactured at Ben Venue followed, which, in the case of Caelyx, led the CHMP to recommend on 15 March 2012 the transfer of the manufacturing operation to an alternative site.

What are the new recommendations on use for Caelyx?

The CHMP has agreed to the transfer of the sterile operation for Caelyx vials for injection to a new manufacturing site. Any Caelyx for which the sterile operation was carried out at Ben Venue is being withdrawn from the market and is being replaced by Caelyx supplied by the new manufacturing site. Based on information provided by the company, the supply of Caelyx is expected to improve and the CHMP no longer considers it necessary to restrict the use of Caelyx to existing patients. It recommends that Caelyx may also be used to start treatment. However, priority should be given to existing patients and new patients for whom no alternative treatment is available.

To ensure that any patient who has started or will start treatment with Caelyx is able to complete a full course of treatment, a new web-based ordering and reservation system, 'Caelyx Managed Access', is being introduced to help manage the allocation of the medicine in the EU.

What are the recommendations for patients and healthcare professionals?

- New patients may be started on Caelyx. However, priority should be given to existing patients and new patients for whom no alternative treatment is available.
- Healthcare professionals will need to use Caelyx Managed Access to order Caelyx for their patients. A letter is being sent out to healthcare professionals in EU with further details.

Further information on Caelyx can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.

[2] http://www.ema.europa.eu/docs/en_GB/document_library/Medicine_QA/2012/03/WC500124203.pdf