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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.

Shortage of Caelyx (doxorubicin hydrochloride)

The European Medicines Agency is aware of a shortage of the anticancer medicine Caelyx in several EU Member States. The Agency's Committee for Medicinal Products for Use (CHMP) is recommending that patients already receiving treatment with Caelyx be given priority and that alternative treatments be considered for new patients.

What is Caelyx?

Caelyx is an anti-cancer medicine that contains the active substance doxorubicin hydrochloride. It is available as a concentrate to be made up into a solution for infusion (drip into a vein).

Caelyx 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).

The active substance, doxorubicin hydrochloride, has been available since the 1960s. In Caelyx, it is contained within 'pegylated liposomes' (tiny fatty spheres that are coated with a chemical called polyethylene glycol). This reduces the rate at which it is broken down, allowing it to circulate in the blood for longer.

What is the cause of the supply problem and how long will it last?

The company that markets Caelyx, Janssen-Cilag, informed the Agency that problems with capacity at Ben Venue Laboratories, USA, where the medicine is manufactured, and investigations relating to the manufacturing process have delayed the release of batches of Caelyx to the EU market. Intermittent supply problems may persist for the remainder of the year.

As Caelyx is also used in combination with some other anticancer medicines, their use may be affected by the shortage.

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What are the recommendations of the CHMP to cope with the shortage?

Doctors will need to make treatment decisions on an individual patient basis after a thorough discussion of the available options. The following need to be considered:

- During the shortage, priority should be given to continuing the treatment of patients already being treated with Caelyx. No new patients should be started on Caelyx, unless there are no other treatment options.
- Due to the limited availability of Caelyx, it will be provided to patients after an individual assessment of their needs. The company will work with pharmacists and physicians to ensure that this is implemented.
- Patients already on Caelyx should be reassured that the supply problems are not due to concerns over safety or quality of the medicine.
- Medicines containing non-liposomal and non-pegylated forms of doxorubicin are not bioequivalent to Caelyx and should only be used as an alternative after a consideration of their benefits and risks to the individual patient.
- Non-anthracycline anticancer medicines may be considered as an alternative treatment.

The Committee is working closely with Janssen-Cilag to ensure that normal supply is resumed as soon as possible in the interest of patients. The Committee has also agreed that the company should provide a letter to the healthcare professionals in the EU, explaining the supply situation in their countries together with recommendations to manage the situation.

The current European public assessment report for Caelyx can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.