



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Caelyx pegylated liposomal<sup>1</sup> (*doxorubicin*)

An overview of Caelyx pegylated liposomal and why it is authorised in the EU

### What is Caelyx pegylated liposomal and what is it used for?

Caelyx pegylated liposomal is a medicine used to treat the following types of cancer in adults:

- metastatic breast cancer in patients at risk of heart problems. 'Metastatic' means the cancer has spread to other parts of the body. Caelyx pegylated liposomal is used on its own for this disease;
- advanced ovarian cancer in women whose previous treatment including a platinum-based cancer medicine has stopped working;
- Kaposi's sarcoma in patients with AIDS who have very damaged immune system. Kaposi's sarcoma is a cancer that causes abnormal tissue to grow under the skin, on moist body surfaces or on internal organs;
- multiple myeloma (a cancer of the cells in the bone marrow), in patients with progressive disease who have received at least one other treatment in the past and have already had a bone marrow transplantation or are unsuitable for it. Caelyx pegylated liposomal is used in combination with bortezomib (another cancer medicine).

Caelyx pegylated liposomal contains the active substance doxorubicin.

### How is Caelyx pegylated liposomal used?

Caelyx pegylated liposomal can only be obtained with a prescription. It should only be given under the supervision of a doctor who is qualified in the use of cytotoxic (cell-killing) medicines. It cannot be interchanged with other medicines that contain doxorubicin.

The dose of Caelyx pegylated liposomal depends on the condition it is used for and is calculated on the basis of the patient's weight and height. The doctor may stop treatment or reduce the dose if certain side effects occur or if the patient has liver problems.

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<sup>1</sup> Previously known as Caelyx.

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**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

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For more information about using Caelyx pegylated liposomal, see the package leaflet or contact your doctor or pharmacist.

## **How does Caelyx pegylated liposomal work?**

Doxorubicin, the active substance in Caelyx pegylated liposomal, is a cytotoxic medicine that belongs to the group 'anthracyclines'. It interferes with the DNA in cells, preventing them from making more copies of DNA and making proteins. This means that cancer cells cannot divide and eventually die. Caelyx pegylated liposomal builds up in areas in the body where the blood vessels have an abnormal shape, such as within tumours, where its action is concentrated.

Doxorubicin has been available since the 1960s. In Caelyx pegylated liposomal, it is enclosed in 'pegylated liposomes' (tiny fat particles coated with a substance called polyethylene glycol). This slows down removal of the medicine, allowing it to circulate in the blood for longer. It also reduces its effects on healthy tissues and cells, so it is less likely to cause some side effects.

## **What benefits of Caelyx pegylated liposomal have been shown in studies?**

Caelyx pegylated liposomal has been studied in a total of 2,512 patients in seven main studies.

For metastatic breast cancer, in a study involving 509 women, Caelyx pegylated liposomal was as effective as standard doxorubicin: the time until the disease got worse was around 7.5 months in both groups. However, patients receiving Caelyx pegylated liposomal were less likely to have heart problems.

For advanced ovarian cancer, in a study involving 474 women who had received platinum-based chemotherapy in the past, Caelyx pegylated liposomal was as effective as topotecan (another cancer medicine) in extending time until the disease got worse.

For AIDS-related Kaposi's sarcoma, the effectiveness of Caelyx pegylated liposomal was studied in two studies involving 384 patients, including 77 who had received treatment before. Around 70% of the patients had a complete or partial response to treatment, with similar results in the study of patients who had been treated before. In additional studies involving a total of 499 patients, Caelyx pegylated liposomal was more effective than either a combination of standard doxorubicin, bleomycin and vincristine (other cancer medicines) or a combination of bleomycin and vincristine.

For multiple myeloma, in a study involving 646 patients, the time until the disease got worse with a Caelyx pegylated liposomal and bortezomib was 9.3 months compared with 6.5 months in patients treated with bortezomib alone.

## **What are the risks associated with Caelyx pegylated liposomal?**

The side effects with Caelyx pegylated liposomal depend on the type of cancer being treated. The most common side effect with Caelyx pegylated liposomal (which may affect more than 1 in 10 people) is nausea (feeling sick). Other very common side effects include palmar-plantar erythrodysesthesia syndrome (redness and pain on the hands and feet), vomiting, stomatitis (inflammation of the lining of the mouth), rash, weakness, low blood cell counts, loss of appetite, hair loss, tiredness, diarrhoea, constipation and mucositis (inflammation of the mouth and throat).

Caelyx pegylated liposomal must not be used to treat Kaposi's sarcoma that could be treated effectively with 'local' treatments that only affect the site of the tumour or with alfa interferon treatment.

For the full list of side effects and restrictions of Caelyx pegylated liposomal, see the package leaflet.

### **Why is Caelyx pegylated liposomal authorised in the EU?**

The European Medicines Agency decided that Caelyx pegylated liposomal's benefits are greater than its risks and it can be authorised for use in the EU.

### **What measures are being taken to ensure the safe and effective use of Caelyx pegylated liposomal?**

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Caelyx pegylated liposomal have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Caelyx pegylated liposomal are continuously monitored. Side effects reported with Caelyx pegylated liposomal are carefully evaluated and any necessary action taken to protect patients.

### **Other information about Caelyx pegylated liposomal**

Caelyx pegylated liposomal received a marketing authorisation valid throughout the EU on 21 June 1996.

Further information on Caelyx pegylated liposomal can be found on the Agency's website:

[ema.europa.eu/medicines/human/EPAR/caelyx](http://ema.europa.eu/medicines/human/EPAR/caelyx).

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