Caelyx
doxorubicin hydrochloride

This is a summary of the European public assessment report (EPAR) for Caelyx. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Caelyx.

What is Caelyx?

Caelyx is concentrate to be made up into a solution for infusion (drip into a vein). It contains the active substance doxorubicin hydrochloride (2 mg/ml).

What is Caelyx used for?

Caelyx is 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 is used on its own for this disease;
- advanced ovarian cancer (cancer of the ovary) in women whose previous treatment including a platinum-based anticancer medicine has stopped working;
- Kaposi’s sarcoma (a cancer of the blood vessels) in patients with acquired immune deficiency syndrome (AIDS) who have very damaged immune systems and extensive sarcoma on the skin, the moist body surfaces or the 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 undergone or are unsuitable for a bone marrow transplant. Caelyx is used in combination with bortezomib (another anticancer medicine).

The medicine can only be obtained with a prescription.
**How is Caelyx used?**

Caelyx should 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 containing doxorubicin hydrochloride.

The recommended starting dose of Caelyx for breast or ovarian cancer is 50 mg per square metre body surface area (calculated using the patient’s height and weight) every four weeks for as long as the disease does not get worse and the patient can tolerate the treatment. For Kaposi’s sarcoma, the dose is 20 mg/m² every two to three weeks for two to three months, and for multiple myeloma, it is 30 mg/m² on day four of each three-week cycle of bortezomib treatment, for as long as the patient continues to benefit from the treatment and can tolerate it.

Treatment should be stopped or the dose reduced in patients who experience certain side effects or who have liver problems. Caelyx is not recommended for patients whose spleen has been removed. For more information, see the package leaflet.

**How does Caelyx work?**

The active substance in Caelyx, doxorubicin hydrochloride, is a cytotoxic medicine that belongs to the group ‘anthracyclines’. It works by interfering with the DNA within cells, preventing them from making more copies of DNA and making proteins. This means that cancer cells cannot divide and eventually die. Caelyx accumulates in areas in the body where the blood vessels have an abnormal shape, such as within tumours, where its action is concentrated.

Doxorubicin hydrochloride has been available since the 1960s. In Caelyx, it is contained in ‘pegylated liposomes’ (tiny fatty spheres that are coated with a chemical called polyethylene glycol). This reduces the rate at which the active substance is broken down, allowing it to circulate in the blood for longer. It also reduces its effects on non-cancer tissues and cells, so it is less likely to cause some side effects.

**How has Caelyx been studied?**

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

For metastatic breast cancer, Caelyx has been compared with standard doxorubicin in one main study involving 509 women.

For advanced ovarian cancer, Caelyx has been compared with topotecan (another anticancer medicine) in one study involving 474 women who had received platinum-based chemotherapy in the past.

For AIDS-related Kaposi’s sarcoma, the effectiveness of Caelyx was studied in two main studies involving 384 patients, including 77 who had received treatment before. Further studies compared Caelyx with the combination of doxorubicin, bleomycin and vincristine (other anticancer medicines) in 258 patients and with the combination of bleomycin and vincristine in 241 patients.

For multiple myeloma, the effectiveness of the combination of Caelyx and bortezomib was compared with that of bortezomib alone in 646 patients.

The main measure of effectiveness was time until the disease got worse or, for Kaposi’s sarcoma, the number of patients who responded to treatment.
What benefit has Caelyx shown during the studies?

In the treatment of breast cancer, Caelyx 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 were less likely to experience heart problems.

For ovarian cancer, Caelyx was as effective as topotecan in extending time until the disease got worse.

For Kaposi’s sarcoma, 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. The additional studies showed that Caelyx was also more effective than the comparator combinations.

For multiple myeloma, adding Caelyx to bortezomib increased the time until the disease got worse from 6.5 to 9.3 months.

What is the risk associated with Caelyx?

The side effects with Caelyx depend on the type of cancer being treated. The most common side effect seen in all types of cancer (in more than 1 patient in 10) is nausea (feeling sick). Other very common side effects include palmar-plantar erythrodysaesthesia syndrome (redness and pain on the hands and feet), vomiting, stomatitis (inflammation of the lining of the mouth), rash, asthenia (weakness), low blood cell counts, loss of appetite, alopecia (hair loss), fatigue (tiredness), diarrhoea, constipation and mucositis (inflammation of the mouth and throat). For the full list of all side effects reported with Caelyx, see the package leaflet.

Caelyx should not be used in people who may be hypersensitive (allergic) to doxorubicin hydrochloride or any of the other ingredients. Caelyx 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 whole-body alfa interferon treatment.

Why has Caelyx been approved?

The CHMP decided that Caelyx’s benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Caelyx

The European Commission granted a marketing authorisation valid throughout the European Union for Caelyx on 21 June 1996. The marketing authorisation holder is Janssen-Cilag International NV. The marketing authorisation is valid for an unlimited period.

The full EPAR for Caelyx can be found on the Agency’s website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Caelyx, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 10-2010.