



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/631375/2019  
EMA/H/C/000297

## Myocet liposomal<sup>1</sup> (*doxorubicin*)

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

### What is Myocet liposomal and what is it used for?

Myocet liposomal is a cancer medicine for use with cyclophosphamide (another cancer medicine) to treat women with metastatic breast cancer. 'Metastatic' means that the cancer has spread to other parts of the body.

Myocet liposomal contains the active substance doxorubicin.

### How is Myocet liposomal used?

Myocet liposomal can only be obtained with a prescription and it should be given under the supervision of a doctor experienced in the use of cytotoxic chemotherapy (cell-killing cancer treatment). It should be given in a specialised unit for giving chemotherapy.

Myocet liposomal is given every 3 weeks by infusion (drip) into a vein over an hour. The dose is calculated on the basis of the woman's weight and height. The doctor may interrupt treatment or reduce the dose if certain side effects develop.

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

### How does Myocet liposomal work?

The active substance in Myocet liposomal, doxorubicin, is a cytotoxic (cell-killing) medicine that belongs to the group 'anthracyclines'. It works by interfering with the DNA in cells, preventing the cells from making copies of DNA and from making proteins. This means that cancer cells cannot divide and eventually die. Because Myocet liposomal builds up in tumours, its effect is concentrated there.

Doxorubicin has been available since the 1960s. In Myocet liposomal, doxorubicin is enclosed in tiny fat particles called 'liposomes'. This helps to protect the heart and the gut from doxorubicin's harmful effects and so reduces side effects.

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



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

Three main studies involving a total of 681 women with metastatic breast cancer found treatment with Myocet liposomal for 6 weeks at least as effective as standard (non-liposomal) doxorubicin or another medicine used for the condition.

In the first study, the disease improved in 43% of women receiving either Myocet liposomal or standard doxorubicin, both combined with cyclophosphamide. In the second study, 26% of women receiving either Myocet liposomal alone or standard doxorubicin alone improved with treatment. In the third study, the disease improved in 46% of women receiving Myocet liposomal with cyclophosphamide compared with 39% of women receiving epirubicin (a medicine that works in the same way as doxorubicin) with cyclophosphamide.

Heart problems occurred less often in patients receiving Myocet liposomal than in those receiving standard doxorubicin.

## **What are the risks associated with Myocet liposomal?**

The most common side effects with Myocet liposomal (which may affect more than 1 in 10 people) are neutropenic fever (fever associated with low levels of neutrophils, a type of white blood cell), infection, neutropenia (low levels of neutrophils), thrombocytopenia (low blood platelet counts), anaemia (low red blood cell counts), leucopenia (low white blood cell counts), loss of appetite, nausea (feeling sick), vomiting, stomatitis (inflammation of the lining of the mouth), mucositis (inflammation of the moist body surfaces), diarrhoea, hair loss, weakness, fever, pain and rigors (shaking chills).

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

## **Why is Myocet liposomal authorised in the EU?**

Myocet liposomal has a lower risk of heart problems than conventional doxorubicin, while both medicines are similarly effective. The European Medicines Agency therefore decided that Myocet 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 Myocet liposomal?**

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

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

## **Other information about Myocet liposomal**

Myocet liposomal received a marketing authorisation valid throughout the EU on 13 July 2000.

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

[ema.europa.eu/medicines/human/EPAR/myocet-liposomal](http://ema.europa.eu/medicines/human/EPAR/myocet-liposomal).

This overview was last updated in 11-2019.