EMA/949959/2011
EMEA/H/C/002317

EPAR summary for the public

Docetaxel Mylan

docetaxel

This is a summary of the European public assessment report (EPAR) for Docetaxel Mylan. 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 Docetaxel Mylan.

What is Docetaxel Mylan?

Docetaxel Mylan is a medicine that contains the active substance docetaxel. It is available as a concentrate to make up into a solution for infusion (drip into a vein).

Docetaxel Mylan is a 'generic medicine'. This means that Docetaxel Mylan is similar to a 'reference medicine' already authorised in the European Union (EU) called Taxotere. For more information on generic medicines, see the question-and-answer document here.

What is Docetaxel Mylan used for?

Docetaxel Mylan is used to treat the following types of cancer:

- breast cancer. Docetaxel Mylan can be used on its own after other treatments have failed. It can also be used with other anticancer medicines (doxorubicin, cyclophosphamide, trastuzumab or capecitabine) in patients who have not yet received any treatment for their cancer or after other treatments have failed, depending on the type and stage of the breast cancer being treated;
- non-small-cell lung cancer. Docetaxel Mylan can be used on its own after other treatments have failed. It can also be used with cisplatin (another anticancer medicine) in patients who have not yet received any treatment for their cancer;
- prostate cancer, when the cancer does not respond to hormonal treatment. Docetaxel Mylan is used with prednisone or prednisolone (anti-inflammatory medicines);

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

- gastric adenocarcinoma (a type of stomach cancer) in patients who have not yet received any treatment for their cancer. Docetaxel Mylan is used with cisplatin and 5-fluorouracil (other anticancer medicines);
- head and neck cancer in patients whose cancer is advanced (has started to spread). Docetaxel Mylan is used with cisplatin and 5-fluorouracil.

For full details, see the summary of product characteristics (also part of the EPAR).

The medicine can only be obtained with a prescription.

How is Docetaxel Mylan used?

Docetaxel Mylan should be used in wards specialising in chemotherapy (medicines to treat cancer) under the supervision of a doctor who is qualified in the use of chemotherapy.

Docetaxel Mylan is given as a one-hour infusion every three weeks. The dose, duration of treatment and the medicines it is used with depend on the type of cancer being treated. Docetaxel Mylan is only used when the neutrophil count (the level of a type of white blood cell in the blood) is normal (at least 1,500 cells/mm^3). Dexamethasone (an anti-inflammatory medicine) should also be given to the patient, starting on the day before the Docetaxel Mylan infusion. For more information, see the summary of product characteristics.

How does Docetaxel Mylan work?

The active substance in Docetaxel Mylan, docetaxel, belongs to the group of anticancer medicines known as the taxanes. Docetaxel blocks the ability of cells to destroy the internal 'skeleton' that allows them to divide and multiply. With the skeleton still in place, the cells cannot divide and they eventually die. Docetaxel also affects non-cancer cells such as blood cells, which can cause side effects.

How has Docetaxel Mylan been studied?

The company provided data from the published literature on docetaxel. The company also showed that the Docetaxel Mylan solution for infusion has comparable quality to that of Taxotere. No additional studies were needed as Docetaxel Mylan is a generic medicine that is given by infusion and contains the same active substance as the reference medicine, Taxotere.

What are the benefits and risks of Docetaxel Mylan?

Because Docetaxel Mylan is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why has Docetaxel Mylan been approved?

The CHMP concluded that, in accordance with EU requirements, Docetaxel Mylan has been shown to be comparable to Taxotere. Therefore, the CHMP's view was that, as for Taxotere, the benefit outweighs the identified risk. The Committee recommended that Docetaxel Mylan be given marketing authorisation.

Other information about Docetaxel Mylan

The European Commission granted a marketing authorisation valid throughout the European Union for Docetaxel Mylan on 31 January 2012.

The full EPAR for Docetaxel Mylan 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 Docetaxel Mylan, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 12-2011.