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EPAR summary for the public

Docetaxel Kabi

docetaxel

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

What is Docetaxel Kabi?

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

Docetaxel Kabi is a 'generic medicine'. This means that Docetaxel Kabi 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 Kabi used for?

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

- breast cancer. Docetaxel Kabi 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 Kabi 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 Kabi is used with prednisone or prednisolone (anti-inflammatory medicines);

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

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

Docetaxel Kabi 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 Kabi 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). An anti-inflammatory medicine such as dexamethasone should also be given to the patient, starting on the day before the Docetaxel Kabi infusion. For more information, see the summary of product characteristics.

How does Docetaxel Kabi work?

The active substance in Docetaxel Kabi, 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 Kabi been studied?

The company provided data from published literature on docetaxel. The company also showed that the Docetaxel Kabi solution for infusion has comparable quality to that of Taxotere. No additional studies were needed as Docetaxel Kabi 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 Kabi?

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

Why has Docetaxel Kabi been approved?

The CHMP concluded that, in accordance with EU requirements, Docetaxel Kabi 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 Kabi be given marketing authorisation.

Other information about Docetaxel Kabi

The European Commission granted a marketing authorisation valid throughout the European Union for Docetaxel Kabi on 22 May 2012.

The full EPAR for Docetaxel Kabi 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 Kabi, 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 04-2012.