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Docetaxel Kabi (*docetaxel*)

An overview of Docetaxel Kabi and why it is authorised in the EU

What is Docetaxel Kabi and what is it used for?

Docetaxel Kabi is a cancer medicine 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 cancer medicines (capecitabine, cyclophosphamide, doxorubicin or trastuzumab) in patients who have not yet received 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 cancer medicine) in patients who have not yet received any treatment for their cancer;
- prostate cancer that has spread to other parts of the body (metastatic). Docetaxel Kabi is used with androgen-deprivation therapy (therapy greatly reducing the body's production of testosterone) when such treatment still works. Docetaxel Kabi is used with prednisone or prednisolone (anti-inflammatory medicines) when the cancer is castration resistant (androgen-deprivation therapy does not work);
- metastatic gastric adenocarcinoma (a stomach cancer) in patients who have not yet received any treatment for metastatic cancer. Docetaxel Kabi is used with cisplatin and fluorouracil (other cancer 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 fluorouracil.

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.

Docetaxel Kabi contains the active substance docetaxel.

How is Docetaxel Kabi used?

Docetaxel Kabi can only be obtained with a prescription and should only be used in units specialising in giving chemotherapy (medicines to treat cancer) under the supervision of a doctor who is qualified in the use of chemotherapy.

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Docetaxel Kabi is given as a 1-hour infusion every 3 weeks. The dose, duration of treatment and the medicines it is used with depend on the type of cancer being treated and the patient's weight and height. An anti-inflammatory medicine such as dexamethasone should also be given to the patient, starting on the day before the Docetaxel Kabi infusion. The dose of Docetaxel Kabi may need to be reduced, or treatment interrupted or discontinued, if the patient develops certain side effects.

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

How does Docetaxel Kabi work?

The active substance in Docetaxel Kabi, docetaxel, belongs to the group of cancer medicines known as taxanes. Docetaxel blocks the ability of cells to break down the internal 'skeleton' that allows them to divide. With the skeleton still in place, the cells cannot divide and they eventually die. Because docetaxel works on dividing cells, it affects non-cancer cells such as blood cells, which can cause side effects.

How has Docetaxel Kabi been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Taxotere, and do not need to be repeated for Docetaxel Kabi.

As for every medicine, the company provided studies on the quality of Docetaxel Kabi. There was no need for 'bioequivalence' studies to investigate whether Docetaxel Kabi is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Docetaxel Kabi is given by infusion into a vein, so the active substance is delivered straight into the bloodstream.

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 is Docetaxel Kabi authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Docetaxel Kabi has been shown to be comparable to Taxotere. Therefore, the Agency's view was that, as for Taxotere, the benefits of Docetaxel Kabi outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Docetaxel Kabi?

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

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

Other information about Docetaxel Kabi

Docetaxel Kabi received a marketing authorisation valid throughout the EU on 22 May 2012.

Further information on Docetaxel Kabi can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/docetaxel-kabi. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 04-2020.