EMA/112747/2011
EMEA/H/C/001107

Docetaxel Teva (*docetaxel*)

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

What is Docetaxel Teva and what is it used for?

Docetaxel Teva is a cancer medicine used to treat the following types of cancer:

- breast cancer. Docetaxel Teva can be used on its own after other treatments have failed. It can also be used with other cancer medicines (doxorubicin, cyclophosphamide, trastuzumab or capecitabine) in patients who have not 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 Teva 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 received any treatment for their cancer;
- prostate cancer that has spread to other parts of the body (metastatic). Docetaxel Teva is used with androgen-deprivation therapy (therapy to greatly reduce the body's production of testosterone) when such treatment still works. Docetaxel Teva 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 Teva 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 Teva is used with cisplatin and fluorouracil.

Docetaxel Teva is a 'generic medicine'. This means that Docetaxel Teva contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Taxotere. For more information on generic medicines, see the question-and-answer document here.

Docetaxel Teva contains the active substance docetaxel.

How is Docetaxel Teva used?

Docetaxel Teva can only be obtained with a prescription and should 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 Teva is given as a 1-hour infusion (drip) into a vein 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 Teva infusion. The dose of Docetaxel Teva may need to be reduced, or treatment interrupted or discontinued, if the patient develops certain side effects.

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

How does Docetaxel Teva work?

The active substance in Docetaxel Teva, 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 intact, the cells cannot divide and they eventually die. Because docetaxel works on dividing cells, it also affects non-cancer cells such as blood cells, which can cause side effects.

How has Docetaxel Teva 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 Teva.

As for every medicine, the company provided studies on the quality of Docetaxel Teva. There was no need for 'bioequivalence' studies to investigate whether Docetaxel Teva is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Docetaxel Teva 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 Teva?

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

Why is Docetaxel Teva authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Docetaxel Teva has been shown to be comparable to Taxotere. Therefore, the Agency's view was that, as for Taxotere, the benefits of Docetaxel Teva 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 Teva?

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

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

Other information about Docetaxel Teva

Docetaxel Teva received a marketing authorisation valid throughout the EU on 26 January 2010.

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

This overview was last updated in 07-2020.