



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Docetaxel Zentiva¹ (*docetaxel*)

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

What is Docetaxel Zentiva and what is it used for?

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

- breast cancer. Docetaxel Zentiva 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 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 Zentiva 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, when the cancer has spread to other parts of the body (metastatic). Docetaxel Zentiva is used with prednisone or prednisolone (anti-inflammatory medicines) when the cancer cannot be treated by greatly reducing the body's production of testosterone (castration-resistant prostate cancer). It can also be used with androgen-deprivation therapy when hormonal treatment still works (hormone-sensitive prostate cancer);
- gastric adenocarcinoma (a type of stomach cancer) in patients who have not yet received any treatment for their cancer. Docetaxel Zentiva 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 Zentiva is used with cisplatin and fluorouracil.

Docetaxel Zentiva contains the active substance docetaxel.

How is Docetaxel Zentiva used?

Docetaxel Zentiva can only be obtained with a prescription and is 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.

¹ Previously known as Docetaxel Winthrop.



Docetaxel Zentiva 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 Zentiva infusion.

The dose of Docetaxel Zentiva may need to be reduced, or treatment interrupted or discontinued, if the patient develops certain side effects.

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

How does Docetaxel Zentiva work?

The active substance in Docetaxel Zentiva, 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 also affects non-cancer cells such as blood cells, which can cause side effects.

What benefits of Docetaxel Zentiva have been shown in studies?

Docetaxel Zentiva has been studied in over 4,000 breast-cancer patients, around 2,000 non-small-cell-lung-cancer patients, around 2,700 prostate-cancer patients, 457 gastric-adenocarcinoma patients and 897 head- and neck-cancer patients. In most of these studies, Docetaxel Zentiva was combined with other anticancer treatments and compared either with the medicines it is used in combination with or with a combination of different treatments.

Adding Docetaxel Zentiva to other cancer treatments increased the number of patients whose cancer responded to treatment, how long the patients lived without their disease getting worse and how long the patients survived, in all five types of cancer. When used on its own, Docetaxel Zentiva was at least as effective as and sometimes more effective than the comparator medicines in breast cancer, and more effective than best supportive care (any medicines or treatment to help patients, but not other cancer medicines) in lung cancer.

What are the risks associated with Docetaxel Zentiva?

The most common side effects with Docetaxel Zentiva (which may affect more than 1 in 10 people) are neutropenia (low levels of neutrophils, white blood cells that fight infection), anaemia (low red blood cell counts), stomatitis (inflammation of the lining of the mouth), diarrhoea, nausea (feeling sick), vomiting, alopecia (hair loss) and asthenia (weakness). These side effects may be more severe when Docetaxel Zentiva is used with other cancer medicines. For the full list of side effects with Docetaxel Zentiva, see the package leaflet.

Docetaxel Zentiva must not be used in patients who have a neutrophil count of less than 1,500 cells/mm³ or who have severe problems with their liver. For the full list of restrictions, see the package leaflet.

Why is Docetaxel Zentiva authorised in the EU?

The European Medicines Agency decided that Docetaxel Zentiva'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 if Docetaxel Zentiva?

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

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

Other information about Docetaxel Zentiva

Docetaxel Zentiva received a marketing authorisation valid throughout the EU on 20 April 2007. This authorisation was based on the authorisation granted to Taxotere in 1995 ('informed consent').

Further information on Docetaxel Zentiva can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/docetaxel-zentiva.

This overview was last updated in 11-2019.