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EPAR summary for the public

Docetaxel Teva Pharma

docetaxel

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

What is Docetaxel Teva Pharma?

Docetaxel Teva Pharma is a medicine that contains the active substance docetaxel. It is available as a concentrate and a solvent that are made up into a solution for infusion (drip into a vein).

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

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

- breast cancer. Docetaxel Teva Pharma is used on its own after other treatments have failed;
- non-small cell lung cancer. Docetaxel Teva Pharma 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 Teva Pharma is used with prednisone or prednisolone (anti-inflammatory medicines);
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How is Docetaxel Teva Pharma used?

Docetaxel Teva Pharma 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 Teva Pharma 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 Teva Pharma 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/mm³). Dexamethasone (an anti-inflammatory medicine) should also be given to the patient, starting on the day before the Docetaxel Teva Pharma infusion. For more information, see the summary of product characteristics.

How does Docetaxel Teva Pharma work?

The active substance in Docetaxel Teva Pharma, 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 Teva Pharma been studied?

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

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

Why has Docetaxel Teva Pharma been approved?

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

Other information about Docetaxel Teva Pharma

The European Commission granted a marketing authorisation valid throughout the European Union for Docetaxel Teva Pharma to Teva Pharma B.V. on 21 January 2011. The marketing authorisation is valid for five years, after which it can be renewed.

The full EPAR for Docetaxel Teva Pharma 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 Teva Pharma, 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 11-2010.

Medicinal product no longer authorised