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EPAR summary for the public

Docefrez

docetaxel

This document is a summary of the European Public Assessment Report (EPAR) for Docefrez. 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 Docefrez.

What is Docefrez?

Docefrez is a powder and solvent that is made up to a solution for infusion (drip into a vein). It contains the active substance docetaxel.

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

Docefrez is used to treat the following types of cancer:

- breast cancer. Docefrez 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. Docefrez 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. Docefrez 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. Docefrez is used with cisplatin and 5-fluorouracil (other anticancer medicines);
- head and neck cancer in patients whose cancer is advanced (has started to spread). Docefrez 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 Docefrez used?

Docefrez 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.

Docefrez 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. Docefrez 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). Dexamethasone (an anti-inflammatory medicine) should also be given to the patient, starting on the day before the Docefrez infusion. For more information, see the Summary of Product Characteristics.

How does Docefrez work?

The active substance in Docefrez, 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 Docefrez been studied?

Because Docefrez is a generic medicine, the company provided data on docetaxel from the published literature. No additional studies in patients were needed as Docefrez is given by infusion and contains the same active substance as the reference medicine, Taxotere.

What are the benefit and risk of Docefrez?

Because Docefrez is a generic medicine, its benefit and risk are taken as being the same as the reference medicine.

Why has Docefrez been approved?

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

Other information about Docefrez:

The European Commission granted a marketing authorisation valid throughout the European Union for Docefrez to Sun Pharmaceutical Industries Europe B.V. on 15 May 2010. The marketing authorisation is valid for five years, after which it can be renewed.

The full EPAR for Docefrez can be found here. For more information about treatment with Docefrez, read the Package Leaflet (also part of the EPAR).

The full EPAR for the reference medicine can also be found on the Agency's website.

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