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EPAR summary for the public

Taxespira[1]

docetaxel

This is a summary of the European public assessment report (EPAR) for Taxespira. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Taxespira.

For practical information about using Taxespira, patients should read the package leaflet or contact their doctor or pharmacist.

What is Taxespira and what is it used for?

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

- breast cancer. Taxespira 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. Taxespira 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 does not respond to hormonal treatment. Taxespira is used with prednisone or prednisolone (anti-inflammatory medicines);
- gastric adenocarcinoma (a type of stomach cancer) in patients who have not yet received any treatment for their cancer. Taxespira is used with cisplatin and 5-fluorouracil (other cancer medicines);

[1] Previously known as Docetaxel Hospira UK Limited.

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- head and neck cancer in patients whose cancer is locally advanced (a cancer that has grown but has not spread). Taxespira is used with cisplatin and 5-fluorouracil.

Taxespira contains the active substance docetaxel and is a 'generic medicine'. This means that Taxespira 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.

How is Taxespira used?

Taxespira is 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.

Taxespira is available as a concentrate for solution for infusion (drip) into a vein and 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. Taxespira 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). An anti-inflammatory medicine such as dexamethasone should also be given to the patient, starting on the day before the Taxespira infusion.

For more information, see the summary of product characteristics.

How does Taxespira work?

The active substance docetaxel, belongs to the group of anticancer medicines known as the taxanes. Docetaxel blocks a stage of cell division, whereby the internal 'skeleton' is dismantled to allow the cell to divide. By keeping the skeleton intact 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 Taxespira been studied?

The company provided data from the published literature on docetaxel. The company also showed that Taxespira solution for infusion has comparable quality to that of Taxotere. No additional studies in humans were needed as Taxespira is a generic medicine that is given by infusion and contains the same active substance as Taxotere.

What are the benefits and risks of Taxespira?

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

Why is Taxespira approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Taxespira 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 Taxespira be approved for use in the EU.

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

A risk management plan has been developed to ensure that Taxespira is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and

the package leaflet for Taxespira, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Taxespira

The European Commission granted a marketing authorisation valid throughout the European Union for Docetaxel Hospira UK Limited on 28 August 2015. The name of the medicine was changed to Taxespira on 12 October 2015.

The full EPAR and risk management plan summary for Taxespira 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 Taxespira, 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 01-2016.