EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2019
EMA/CHMP/510410/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Docetaxel Zentiva

docetaxel

On 19 September 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Docetaxel Zentiva. The marketing authorisation holder for this medicinal product is Zentiva, k.s..

The CHMP adopted an extension to an existing indication as follows:

> "Docetaxel Zentiva in combination with androgen-deprivation therapy (ADT), with or without prednisone or prednisolone, is indicated for the treatment of patients with metastatic hormone-sensitive prostate cancer."

For information, the full indications for Docetaxel Zentiva will be as follows: [2]

> "Breast cancer
>
> Docetaxel Zentiva in combination with doxorubicin and cyclophosphamide is indicated for the adjuvant treatment of patients with:
>
> - operable node positive breast cancer
> - operable node-negative breast cancer
>
> For patients with operable node negative breast cancer, adjuvant treatment should be restricted to patients eligible to receive chemotherapy according to internationally established criteria for primary therapy of early breast cancer (see section 5.1).
>
> Docetaxel Zentiva in combination with doxorubicin is indicated for the treatment of patients with locally advanced or metastatic breast cancer who have not previously received cytotoxic therapy for this condition.
>
> Docetaxel Zentiva monotherapy is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic therapy. Previous chemotherapy should have included an anthracycline or an alkylating agent.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text in bold, removed text as strikethrough

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Docetaxel Zentiva in combination with trastuzumab is indicated for the treatment of patients with metastatic breast cancer whose tumours over express HER2 and who previously have not received chemotherapy for metastatic disease.

Docetaxel Zentiva in combination with capecitabine is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy. Previous therapy should have included an anthracycline.

Non-small cell lung cancer

Docetaxel Zentiva is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of prior chemotherapy.

Docetaxel Zentiva in combination with cisplatin is indicated for the treatment of patients with unresectable, locally advanced or metastatic non-small cell lung cancer, in patients who have not previously received chemotherapy for this condition.

Prostate cancer

Docetaxel Zentiva in combination with prednisone or prednisolone is indicated for the treatment of patients with ~~hormone refractory~~ metastatic **castration-resistant** prostate cancer.

Docetaxel Zentiva in combination with androgen-deprivation therapy (ADT), with or without prednisone or prednisolone, is indicated for the treatment of patients with metastatic hormone-sensitive prostate cancer.

Gastric adenocarcinoma

Docetaxel Zentiva in combination with cisplatin and 5 fluorouracil is indicated for the treatment of patients with metastatic gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for metastatic disease.

Head and neck cancer

Docetaxel Zentiva in combination with cisplatin and 5 fluorouracil is indicated for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck."

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.