28 February 2019
EMA/CHMP/147314/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Pazenir

paclitaxel

On 28 February 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Pazenir, intended for the treatment of metastatic breast cancer and non-small cell lung cancer. The applicant for this medicinal product is Teva B.V.

Pazenir will be available as a 5 mg/ml powder for dispersion for infusion. The active substance of Pazenir is paclitaxel, an antineoplastic agent that belongs to the class known as taxanes (ATC code: L01CD01). Paclitaxel blocks a stage of cell division in which the cell's internal skeleton is dismantled to allow the cell to divide. By keeping this structure intact the cells cannot divide and they eventually die. Pazenir also affects non-cancer cells such as blood and nerve cells, which can cause side effects.

Pazenir is a generic of Abraxane, another nanoparticle albumin-bound paclitaxel, which has been authorised in the EU since 2008. Studies have demonstrated the satisfactory quality of Pazenir. A bioequivalence study versus the reference product Abraxane was not required. This is because Pazenir is administered intravenously and the nanoparticles dissociate rapidly, and also because of the qualitative and quantitative compositions and the nature and behaviour of the products. A question and answer document on generic medicines can be found here.

The full indication is:

> "Pazenir monotherapy is indicated for the treatment of metastatic breast cancer in adult patients who have failed first-line treatment for metastatic disease and for whom standard, anthracycline containing therapy is not indicated (see section 4.4).
>
> Pazenir in combination with carboplatin is indicated for the first-line treatment of non-small cell lung cancer in adult patients who are not candidates for potentially curative surgery and/or radiation therapy."

It is proposed that Pazenir should only be administered under the supervision of a qualified oncologist in units specialised in the administration of cytotoxic agents. It should not be substituted for or with other paclitaxel formulations.

[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

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