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Pazenir (*paclitaxel*)

An overview of Pazenir and why it is authorised in the EU

What is Pazenir and what is it used for?

Pazenir is used to treat the following cancers in adults:

- metastatic breast cancer, when the first treatment has stopped working and standard treatment including an anthracycline (another type of cancer medicine) is not suitable. 'Metastatic' means that the cancer has spread to other parts of the body;
- metastatic adenocarcinoma of the pancreas, as a first treatment in combination with another cancer medicine, gemcitabine;
- non-small cell lung cancer, as a first treatment in combination with the cancer medicine carboplatin when the patient cannot have surgery or radiotherapy.

Pazenir contains the active substance paclitaxel attached to a human protein called albumin and is a 'generic medicine'. This means that Pazenir contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Abraxane. For more information on generic medicines, see the question-and-answer document here.

How is Pazenir used?

Pazenir is given as an infusion into a vein over a period of 30 minutes. The recommended dose depends on the patient's height and weight.

In metastatic breast cancer, Pazenir is given on its own every three weeks.

In metastatic adenocarcinoma of the pancreas, Pazenir is given in 4-week treatment cycles. The medicine is given once a day on days 1, 8 and 15 of each cycle. Immediately after giving Pazenir, gemcitabine should be given.

In non-small cell lung cancer, treatment is carried out in 3-week cycles with Pazenir given on days 1, 8 and 15 of each cycle and carboplatin given on day 1 immediately after Pazenir.

Pazenir should only be given under the supervision of a cancer doctor in clinics that are specialised in giving 'cytotoxic' (cell-killing) medicines. It should not be interchanged with other medicines containing paclitaxel. The medicine can only be obtained with a prescription.

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For more information about using Pazenir, see the package leaflet or contact your doctor or pharmacist.

How does Pazenir work?

The active substance in Pazenir, paclitaxel, belongs to the group of cancer medicines known as the 'taxanes'. 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.

Paclitaxel has been available as a cancer medicine since 1993. In Pazenir, as in its reference medicine Abraxane, paclitaxel is attached to a human protein called albumin in tiny particles known as 'nanoparticles'. This makes it easy to prepare a suspension of paclitaxel, which can be infused into a vein.

How has Pazenir been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Abraxane, and do not need to be repeated for Pazenir.

As for every medicine, the company provided studies on the quality of Pazenir. There was no need for 'bioequivalence' studies to investigate whether Pazenir is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Pazenir is given by infusion into a vein and the nanoparticles it contains rapidly separate into its constituent parts in the same way as Abraxane's.

What are the benefits and risks of Pazenir?

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

Why is Pazenir authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Pazenir has been shown to be comparable to Abraxane. Therefore, the Agency's view was that, as for Abraxane, the benefits of Pazenir outweigh the identified risks and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Pazenir have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Pazenir are continuously monitored. Side effects reported with Pazenir are carefully evaluated and any necessary action taken to protect patients.

Other information about Pazenir

Pazenir received a marketing authorisation valid throughout the EU on 6 May 2019.

Further information on Pazenir can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/pazenir. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 12-2019.