EMA/290084/2024
EMEA/H/C/005997

Apexelsin (*paclitaxel*)

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

What is Apexelsin and what is it used for?

Apexelsin is a cancer medicine used in adults to treat:

- 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.

Apexelsin contains the active substance paclitaxel and is a generic medicine. This means that Apexelsin contains the same active substance and works in the same way as a reference medicine already authorised in the EU. The reference medicine for Apexelsin is Abraxane. For more information on generic medicines, see the question-and-answer document here.

Apexelsin contains the active substance paclitaxel.

How is Apexelsin used?

Apexelsin can only be obtained with a prescription and treatment 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.

Apexelsin is given as an infusion (drip) into a vein over 30 minutes. The recommended dose depends on the patient's height and weight.

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

In metastatic adenocarcinoma of the pancreas, Apexelsin is given in 4-week treatment cycles on days 1, 8 and 15 of each cycle. Gemcitabine is given immediately after Apexelsin.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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

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

How does Apexelsin work?

The active substance in Apexelsin, 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. Apexelsin 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 Apexelsin, unlike conventional paclitaxel-containing medicines, 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 Apexelsin 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 Apexelsin.

As for every medicine, the company provided studies on the quality of Apexelsin. There was no need for bioequivalence studies to investigate whether Apexelsin is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Apexelsin is given by infusion, so the active substance is delivered straight into the bloodstream.

What are the benefits and risks of Apexelsin?

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

Why is Apexelsin authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Apexelsin has been shown to be comparable to Abraxane. Therefore, the Agency's view was that, as for Abraxane, the benefits of Apexelsin 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 Apexelsin?

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

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

Other information about Apexelsin

Apexelsin received a marketing authorisation valid throughout the EU on 24 July 2024.

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

This overview was last updated in 07-2024.