



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 May 2024
EMA/250328/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Apexelsin paclitaxel

On 30 May 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Apexelsin, intended for the treatment of metastatic breast cancer, metastatic adenocarcinoma of the pancreas and non-small cell lung cancer.

The applicant for this medicinal product is WhiteOak Pharmaceutical B.V.

Apexelsin will be available as 5 mg/ml powder for dispersion for infusion. The active substance of Apexelsin is paclitaxel, a taxane antineoplastic agent (ATC code: L01CD01). Paclitaxel interferes with microtubule growth to block cell division and induces apoptosis. Paclitaxel also affects non-cancer cells such as blood and nerve cells, which can cause side effects.

Apexelsin 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 Apexelsin. A bioequivalence study versus the reference product was not required because Apexelsin is administered intravenously and the nanoparticles dissociate rapidly, and because of the qualitative and quantitative comparability of the products. A question and answer document on generic medicines can be found [here](#).

The full indication is:

Apexelsin 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).

Apexelsin in combination with gemcitabine is indicated for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas.

Apexelsin 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.

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



Apexelsin 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.

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.