


Union Register of medicinal products for human use

Product information



Product name:	Apexelsin 	✓ ACTIVE
EU number:	EU/1/24/1835	
Active substance:	Paclitaxel	
Indication:	<p>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).</p> <p>Apexelsin in combination with gemcitabine is indicated for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas.</p> <p>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.</p>	
Marketing Authorisation Holder:	WhiteOak Pharmaceutical B.V. Teleportboulevard 130, Amsterdam, 1043 EJ, Nederland	
ATC:	<p>Anatomical main group: L - Antineoplastic and immunomodulating agents Therapeutic subgroup: L01 - Antineoplastic agents Pharmacological subgroup: L01C - Plant alkaloids and other natural products Chemical subgroup: L01CD - Taxanes Chemical substance: L01CD01 - paclitaxel (See WHO ATC Index)</p>	

Package presentations

Information about presentations can be found in the website of the European Medicines Agency under the section "Product Information". Likewise, presentations on which there has been a Commission decision are referred in the Summary of Product Characteristics (Annex I to the Commission Decision granting the marketing authorisation) which is available in the Union Register.

European Commission procedures

By clicking on the icon, it is possible to download all the linguistic versions of a specific Decision or Annex in a single package.



Close date	Procedure type	EMA number	Decision number	Summary	Decisions	Annexes
26 Jul 2024	Centralised - Authorisation	EMEA/H/C/005997/0000	(2024)5468 of 24 Jul 2024	- ↓	- ↓	- ↓
27 Aug 2024	Centralised - Variation	EMEA/H/C/005997/IAIN/0001/G	-			

Last updated on 03/09/2024.