

## 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:	<p><a href="#">WhiteOak Pharmaceutical B.V.</a> Teleportboulevard 130, Amsterdam, 1043 EJ, Nederland</p>	
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 <a href="#">WHO ATC Index</a>)</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.