EUROPEAN MEDICINES AGENCY
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← Medicines

Naveruclif

paclitaxel

Medicine Human

Authorised

This medicine is authorised for use in the European Union

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Overview

Naveruclif 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.

Naveruclif is a 'generic medicine'. This means that Naveruclif contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Naveruclif is Abraxane. For more

information on generic medicines, see the question-and-answer document here.

Naveruclif contains the active substance paclitaxel attached to a human protein called albumin.

How is Naveruclif used?

How does Naveruclif work?

How has Naveruclif been studied?

What are the benefits and risks of Naveruclif?

Why is Naveruclif authorised in the EU?

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

Other information about Naveruclif

Naveruclif : EPAR - Medicine Overview

Reference Number: EMEA/H/C/006173

English (EN) (166.62 KB - PDF)

First published: 27/02/2024

View

Other languages (22)

Naveruclif : EPAR - Risk-management-plan summary

English (EN) (625.33 KB - PDF)
First published: 27/02/2024

View

Product information

Naveruclif : EPAR - Product Information

English (EN) (775.94 KB - PDF)
First published: 27/02/2024

View

Other languages (24)

05/01/2024

This medicine's product information is available in all **official EU languages**.
Select 'available languages' to access the language you need.

Product information documents contain:

- summary of product characteristics (annex I);
- manufacturing authorisation holder responsible for batch release (annex IIA);
- conditions of the marketing authorisation (annex IIB);
- labelling (annex IIIA);
- package leaflet (annex IIIB).

Naveruclif : EPAR - All Authorised Presentations

Reference Number: EMA/513688/2023

English (EN) (159.09 KB - PDF)

First published: 27/02/2024

View

Other languages (24)

Product details

Name of medicine

Naveruclif

Active substance

paclitaxel

International non-proprietary name (INN) or common name

paclitaxel

Therapeutic area (MeSH)

- Breast Neoplasms
- Pancreatic Neoplasms
- Carcinoma, Non-Small-Cell Lung

Anatomical therapeutic chemical (ATC) code

L01CD01

Pharmacotherapeutic group

Antineoplastic agents

Therapeutic indication

Naveruclif 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).

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

Naveruclif 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.

Authorisation details

EMA product number

EMEA/H/C/006173

Generic

This is a generic medicine, which is developed to be the same as a medicine that has already been authorised, called the reference medicine. A generic medicine contains the same active substance(s) as the reference medicine, and is used at the same dose(s) to treat the same disease(s). For more information, see Generic and hybrid medicines.

Marketing authorisation holder

Accord Healthcare S.L.U.
Edificio Este Planta 6a
World Trade Center
Moll De Barcelona S/n
08039 Barcelona
SPAIN

Opinion adopted

09/11/2023

Opinion status

Positive

Marketing authorisation issued

05/01/2024

Assessment history

Initial marketing authorisation documents

News on Naveruclif

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 6-9 November 2023

10/11/2023

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