

Summary Public Assessment Report

Paklitaxel albumin Reddy

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paclitaxel,

Powder for dispersion for infusion, 5 mg/ml

This is a summary of the public assessment report (PAR) for Paklitaxel albumin Reddy. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Paklitaxel albumin Reddy and what is it used for?

The product is a ‘generic medicine’. This means that it is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Onivyde.

Paklitaxel albumin Reddy is used to treat the following types of cancer:

Breast cancer

- Breast cancer which has spread to other parts of the body (this is called “metastatic” breast cancer).
- Paclitaxel is used in metastatic breast cancer when at least one other therapy has been tried but has not worked and you are unsuitable for treatments containing a group of medicines called “anthracyclines”.
- People with metastatic breast cancer who received paclitaxel where another therapy had failed, were more likely to experience a reduction in tumour size, and lived longer than people who took an alternative therapy.

Pancreatic cancer

- Paclitaxel is used together with a medicine called gemcitabine if you have metastatic cancer of the pancreas. People with metastatic pancreatic cancer (pancreatic cancer that has spread to other parts of the body) who received paclitaxel with gemcitabine in a clinical trial lived longer than people who had only received gemcitabine.

Lung cancer

- Paclitaxel is also used together with a medicine called carboplatin if you have the most common type of lung cancer, called “non-small cell lung cancer”.
- Paclitaxel is used in non-small cell lung cancer where surgery or radiotherapy would not be suitable to treat the disease.

How does Paklitaxel albumin Reddy work?

Paklitaxel albumin Reddy contains, as its active substance, paclitaxel attached to the human protein albumin, in the form of tiny particles known as nanoparticles. Paclitaxel belongs to a group of medicines called “taxanes” used in cancer.

- Paclitaxel is the part of the medicine that affects the cancer, it works by stopping cancer cells from dividing – this means that they die.
- Albumin is the part of the medicine that helps paclitaxel dissolve in the blood and get across the walls of the blood vessels into the tumour. This means that other chemicals that can cause side effects that can be life threatening are not needed. Such side effects occur far less with [Invented name].

How is Paklitaxel albumin Reddy used?

The pharmaceutical form is powder for dispersion for infusion.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Paklitaxel albumin Reddy have been shown in studies?

No additional studies were needed as the product is a generic medicine that is given by infusion and contains the same active substance as the reference medicine, Onivyde.

What are the possible side effects from Paklitaxel albumin Reddy?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Paklitaxel albumin Reddy approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be similar to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Onivyde, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Paklitaxel albumin Reddy?

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

For more details, please see the full PAR for Paklitaxel albumin Reddy on the following website: [MRI - Home](#).

Other information about Paklitaxel albumin Reddy

The full PAR for Paklitaxel albumin Reddy can be found on the following website: [MRI - Home](#). For more information about treatment with Paklitaxel albumin Reddy, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-06.