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Onivyde pegylated liposomal[1] (*irinotecan*)

An overview of Onivyde pegylated liposomal and why it is authorised in the EU

What is Onivyde pegylated liposomal and what is it used for?

Onivyde pegylated liposomal is a cancer medicine used in adults to treat a form of pancreatic cancer called metastatic adenocarcinoma of the pancreas. Metastatic means that the cancer has spread to other parts of the body. Onivyde pegylated liposomal is used together with other cancer medicines:

- oxaliplatin, 5-fluorouracil and leucovorin, in patients whose cancer has never been treated,
- 5-fluorouracil and leucovorin, in patients whose cancer has got worse despite treatment with the cancer medicine gemcitabine.

Onivyde pegylated liposomal contains the active substance irinotecan.

Pancreatic cancer is rare, and Onivyde pegylated liposomal was designated an 'orphan medicine' (a medicine used in rare diseases) on 9 December 2011. Further information on the orphan designation can be found here: ema.europa.eu/medicines/human/orphan-designations/eu311933.

How is Onivyde pegylated liposomal used?

Onivyde pegylated liposomal can only be obtained with a prescription and treatment must be prescribed and given by a doctor experienced in the use of cancer medicines.

Onivyde pegylated liposomal is given as an infusion (drip) into a vein over 90 minutes. The medicine is given every 2 weeks together with the other cancer medicines. Treatment can continue until the cancer gets worse or severe side effects occur.

To avoid nausea, it is recommended that patients be given dexamethasone or a similar medicine at least 30 minutes before the infusion with Onivyde pegylated liposomal. The doctor may have to reduce the dose in patients who develop severe side effects and those with particular genetic characteristics that increase the risk of side effects.

[1] Previously known as Onivyde

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For more information about using Onivyde pegylated liposomal, see the package leaflet or contact your doctor or pharmacist.

How does Onivyde pegylated liposomal work?

The active substance in Onivyde pegylated liposomal, irinotecan, is a cancer medicine that belongs to the group of medicines called topoisomerase inhibitors. It blocks an enzyme called topoisomerase I, which is involved in copying cell DNA needed to make new cells. By blocking the enzyme, cancer cells are prevented from multiplying and they eventually die. In Onivyde pegylated liposomal, irinotecan is enclosed in tiny fat particles called liposomes. The liposomes are expected to accumulate in the tumour and release the medicine slowly over time, thereby decreasing the rate at which irinotecan is removed from the body and allowing it to act for longer.

What benefits of Onivyde pegylated liposomal have been shown in studies?

Studies showed that Onivyde pegylated liposomal given in combination with other cancer medicines increases the survival of patients with metastatic adenocarcinoma of the pancreas.

A main study involved 770 adults with previously untreated metastatic adenocarcinoma of the pancreas. Patients given Onivyde pegylated liposomal together with oxaliplatin, 5-fluorouracil and leucovorin lived for an average of 11.1 months, compared with 9.2 months for patients taking the cancer medicines gemcitabine and nab-paclitaxel (a standard treatment).

Another main study involved 417 adults with metastatic adenocarcinoma of the pancreas whose cancer got worse despite cancer treatment with gemcitabine. Patients given Onivyde pegylated liposomal together with fluorouracil and leucovorin lived for an average of around 6.1 months, compared with 4.2 months for patients taking fluorouracil plus leucovorin, and 4.9 months for patients taking Onivyde pegylated liposomal alone.

What are the risks associated with Onivyde pegylated liposomal?

For the full list of side effects and restrictions with Onivyde pegylated liposomal, see the package leaflet.

In patients whose cancer has not been previously treated, the most common side effects with Onivyde pegylated liposomal (which may affect more than 1 in 5 people) include diarrhoea, nausea (feeling sick), vomiting, loss of appetite, tiredness, weakness, neutropenia (low levels of neutrophils, a type of white blood cell) and anaemia (low levels of red blood cells). The most common serious side effects (which may affect more than 1 in 50 people) include diarrhoea, nausea, vomiting and dehydration.

In patients whose cancer worsened despite treatment with gemcitabine, the most common side effects with Onivyde pegylated liposomal (which may affect more than 1 in 5 people) also include stomatitis (inflammation of the lining of the mouth) and fever. The most common serious side effects (which may affect more than 1 in 50 people) include diarrhoea, nausea, vomiting, neutropenia with fever, fever, sepsis (infections of the blood), pneumonia (infection of the lungs), septic shock (a dangerous drop in blood pressure caused by severe infection), dehydration, kidney failure and thrombocytopenia (low levels of blood platelets).

Onivyde pegylated liposomal must not be given to patients who had a severe hypersensitivity (allergic) reaction to irinotecan in the past or to those who are breastfeeding.

Why is Onivyde pegylated liposomal authorised in the EU?

Onivyde pegylated liposomal, in combination with fluorouracil and leucovorin, increases the survival of patients with metastatic adenocarcinoma of the pancreas whose cancer has never been previously treated. It also increases the survival of patients whose cancer got worse despite treatment with gemcitabine. These patients have limited treatment options and Onivyde pegylated liposomal therefore fulfils an unmet medical need. The side effects of Onivyde pegylated liposomal are similar to those of standard irinotecan and the side effects manageable.

The European Medicines Agency therefore decided that Onivyde pegylated liposomal's benefits are greater than its risks and recommended that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Onivyde pegylated liposomal?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Onivyde pegylated liposomal have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Onivyde pegylated liposomal are continuously monitored. Suspected side effects reported with Onivyde pegylated liposomal are carefully evaluated and any necessary action taken to protect patients.

Other information about Onivyde pegylated liposomal

Onivyde pegylated liposomal received a marketing authorisation valid throughout the EU on 14 October 2016.

Further information on Onivyde pegylated liposomal can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/onivyde-pegylated-liposomal.

This overview was last updated in 04-2024.