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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 that is used 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 fluorouracil and leucovorin (also called folinate) (other medicines used for cancer) in adults whose cancer has got worse despite treatment containing 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 should only be prescribed and given by a doctor who has experience in the use of cancer medicines.

Onivyde pegylated liposomal is available for infusion (drip) into a vein. The dose is calculated on the basis of the patient's weight and height and is given every 2 weeks together with fluorouracil and leucovorin. The doctor may reduce the dose in patients who develop severe side effects and in those with particular genetic characteristics that increase the risk of side effects. 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 'topoisomerase inhibitors'. It blocks an enzyme called topoisomerase I, which is involved in

[1] Previously known as Onivyde

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copying cell DNA needed to make new cells. By blocking the enzyme, cancer cells are prevented from multiplying and they eventually die. In Europe, irinotecan has been authorised for a number of years for the treatment of colorectal cancer. 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?

Onivyde pegylated liposomal was investigated in one main study involving 417 patients with metastatic adenocarcinoma of the pancreas whose cancer got worse despite cancer treatment that contained gemcitabine (another cancer medicine). Patients were given Onivyde pegylated liposomal or fluorouracil plus leucovorin, or the three medicines in combination. The main measure of effectiveness was overall survival (how long the patients lived). The study showed that the addition of Onivyde pegylated liposomal to the fluorouracil plus leucovorin regimen prolonged patients' lives: patients taking the three medicines together lived for 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?

The most common side effects with Onivyde pegylated liposomal (which may affect more than 1 in 5 people) are diarrhoea, nausea (feeling sick), vomiting, loss of appetite, neutropenia (low levels of neutrophils, a type of white blood cell), tiredness, weakness, anaemia (low red blood cell counts), 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) included diarrhoea, nausea and vomiting, neutropenia and fever, infections of blood or lungs (sepsis, pneumonia), shock, dehydration, kidney failure and thrombocytopenia (low levels of blood platelets). For the full list of side effects of Onivyde pegylated liposomal, see the package leaflet.

Onivyde pegylated liposomal must not be given to patients who had a severe hypersensitivity (allergic) reaction to irinotecan in the past and to breastfeeding women. For the full list of restrictions, see the package leaflet.

Why is Onivyde pegylated liposomal authorised in the EU?

The European Medicines Agency decided that Onivyde pegylated liposomal's benefits are greater than its risks and recommended that it be authorised for use in the EU. The Agency considered that the increase in survival when Onivyde pegylated liposomal was used together with fluorouracil and leucovorin was meaningful in previously treated patients with metastatic adenocarcinoma of the pancreas, for whom limited treatment options are available; the safety profile of Onivyde pegylated liposomal is in line with that of standard irinotecan, and the side effects manageable.

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. 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 on14 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 11-2019.