21 March 2024
EMA/CHMP/87106/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Onivyde pegylated liposomal

irinotecan hydrochloride trihydrate

On 21 March 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Onivyde pegylated liposomal. The marketing authorisation holder for this medicinal product is Les Laboratoires Servier.

The CHMP adopted a new indication as follows:

ONIVYDE pegylated liposomal is indicated:

- in combination with oxaliplatin, 5-fluorouracil (5-FU) and leucovorin (LV) for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas,

For information, the full indications for Onivyde pegylated liposomal will be as follows[2]:

ONIVYDE pegylated liposomal is indicated:

- **in combination with oxaliplatin, 5-fluorouracil (5-FU) and leucovorin (LV) for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas,**
- in combination with 5-FU and LV for the treatment of metastatic adenocarcinoma of the pancreas in adult patients who have progressed following gemcitabine based therapy.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text in **bold**

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