October 2020

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

ONIVYDE pegylated liposomal 4.3 mg/ml concentrate for dispersion for infusion, previously ONIVYDE pegylated liposomal 4.3 mg/ml concentrate for solution for infusion (Irinotecan): Interim Supply of Irish Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Servier Laboratories Limited is currently experiencing supply disruption with ONIVYDE pegylated liposomal 4.3 mg/ml concentrate for dispersion for infusion (Irinotecan) in the UK.

To ensure continuity in supply during the current Covid-19 situation, Servier Laboratories Ltd has obtained approval from the MHRA to supply Onivyde product in Irish Packaging, which is expected to be on the UK market from October 2020 to March 2021.

Please note the following:

- This product is licensed under centralised procedure (EU/1/16/1130/001) and is therefore the same in Ireland and in the UK.
- The product from Ireland has the same formulation as the UK product.
- The product from Ireland is manufactured according to the same manufacturing process and quality controls as the UK product.
- There are minor differences between the Irish and UK packaging currently on the market. These differences are detailed below. Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed:

	Ireland	UK
Carton	Ireland POM	United Kingdom POM
	EAN Code: 3664898104027	EAN Code: 3664898103990
	PC: 03664898104027	PC: 03664898103990

	Ireland	UK
Patient Information Leaflet	**Reporting of side effects** If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system via: HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.	**Reporting of side effects** If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.
	Section 6. Content of the pack and other information /…/ For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder: **Ireland** Servier Laboratories (Ireland) Ltd. Tel: +353 (0)1 663 8110	**Section 6. Content of the pack and other information** /…/ For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder. **United Kingdom** Servier Laboratories Ltd Tel: +44 (0)1753 666409
Label	No differences	No differences

- You can refer to the Irish SPC and PIL as the information is identical with the UK SPC and PIL, apart from the advice for side effect reporting.
- This DHPC will be supplied with each UK order of Irish packs.
- Onivyde pegylated liposomal is indicated in the treatment of metastatic adenocarcinoma of the pancreas, in combination with 5-fluorouracil (5-FU) and leucovorin (LV), in adult patients who have progressed following gemcitabine-based therapy.
- The latest approved product information available on the electronic Medicines Compendium and on the Servier UK website includes a recent update not yet implemented on the packaging of products currently on the market. The latest approved product information refers to “Onivyde pegylated liposomal 4.3 mg/ml concentrate for **dispersion** for infusion” while products on the market are still “Onivyde pegylated liposomal 4.3 mg/ml concentrate for **solution** for infusion”.
- Product Information for Onivyde pegylated liposomal (Irinotecan) is available either via
    - The European Medicines Agency website at https://www.ema.europa.eu/en/medicines/human/EPAR/onivyde-pegylated-liposomal
    - The Electronic Medicines Compendium at https://www.medicines.org.uk/emc/product/9200#PRODUCTINFO

- For additional copies of the leaflet, please use the company contact point (see below).
- The MHRA has agreed to an exemption according to Article 63(3) of Council Directive 2001/83/EC, granted in accordance with regulation 266(4)(a) of the Human Medicines Regulations (HMR) 2012, from the obligation that certain particulars should appear on the outer and immediate packaging of Onivyde pegylated liposomal.

Please ensure all relevant staff are made aware of the content of this letter.

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://www.gov.uk/yellowcard, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effect can also be reported by calling 0800 731 6789 for free.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

Company contact point

If you have any questions about this letter or wish more information about ONIVYDE pegylated liposomal, please contact Servier Laboratories Limited Medical Information by

- Telephone: 01753 666409 or
- Email: Medical.Information-UK@Servier.com

Yours faithfully,

Desmond MURPHY
Chief Executive Officer

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