Date: February 2023

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

ONIVYDE pegylated liposomal 4.3 mg/ml concentrate for dispersion for infusion
Interim Supply of Irish packs (common pack for Republic of Ireland and Northern Ireland) 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 Great Britain.

To ensure continuity in supply, Servier Laboratories Ltd has obtained approval from the MHRA to supply Onivyde pegylated liposomal product in Irish Packaging, which is expected to be on the GB market from February to July 2023.

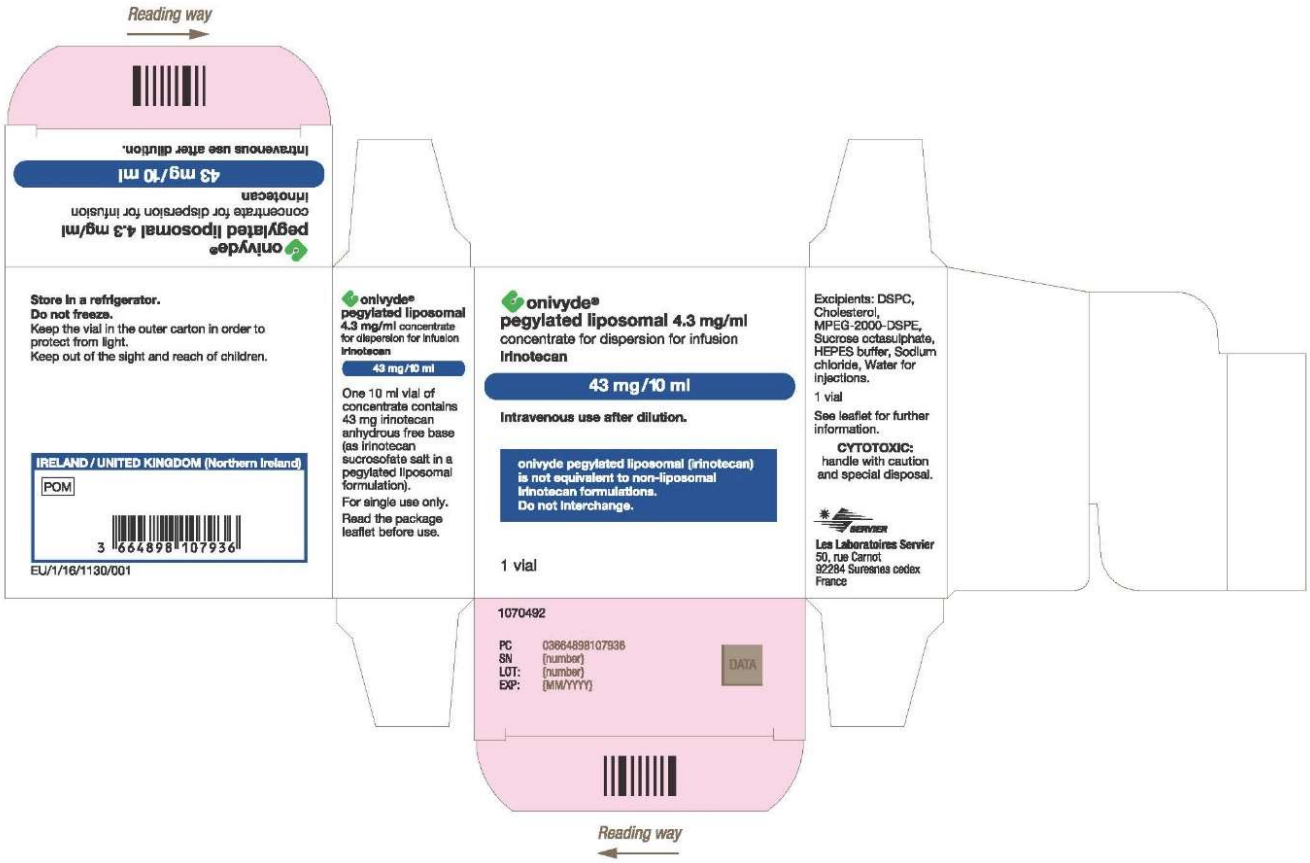
Please note the following:

- The Irish product has the same formulation as the GB product
- The Irish product is manufactured according to the same manufacturing process and quality controls as the UK(GB) product.
- There are minor differences between the Republic of Ireland/Northern Ireland and UK(GB) packaging currently on the market. These differences are detailed below. Please ensure the UK(GB) Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed:

	Ireland/United Kingdom (Northern Ireland)	**UK**
Carton	Ireland/ United Kingdom (Northern Ireland) POM	United Kingdom POM
	EAN Code: 3664898107936	EAN Code: 3664898107899
	PC: 3664898107936	PC: 3664898107899
Patient Information Leaflet	**Section 2 What you need to know before you use ONIVYDE pegylated liposomal** **/…/** **ONIVYDE pegylated liposomal contains sodium** This medicine contains 33.1 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 1.65% of the recommended maximum daily dietary intake of sodium for an adult.	**Section 2 What you need to know before you use ONIVYDE pegylated liposomal** **/…/** **ONIVYDE pegylated liposomal contains sodium** One millilitre of this medicine contains 0.144 mmol (3.31 mg) sodium—keep this in mind if you are on a controlled sodium diet.
	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: Ireland	**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:

	HPRA Pharmacovigilance Website: www.hpra.ie. United Kingdom (Northern Ireland) 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.	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 **United Kingdom** Servier Laboratories Ltd Tel: +44 (0)1 753 666409	**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)1 753 666409
	This leaflet was last revised in July 2021	**This leaflet was last revised in August 2020**
Label	No differences	No differences

- Please see below a mock-up of the Irish packs that will be provided



- This DHPC will be supplied with each UK(GB) 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 includes a recent update not yet implemented on the packaging of products currently on the market.
- Product Information for Onivyde pegylated liposomal (Irinotecan) is available via The Electronic Medicines Compendium at https://www.medicines.org.uk/emc/product/9200#PRODUCTINFO
- For additional copies of the leaflet, please refer to https://www.medicines.org.uk/emc/product/9200/pil or contact the company contact point (see below).
- The MHRA has agreed to an exemption according to 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 effects 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 timing, 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

Digitally signed by Florent TEXIER
Date: 2023.01.19 18:16:05 Z

Florent TEXIER
Managing Director

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