Date: December 2023

Interim Supply of Irish Stock to Mitigate Supply Disruption

Additional Information:
Oncaspar 750 U/ml powder for solution for injection/infusion

To ensure continuity in supply, Servier Laboratories Ltd has obtained approval from the MHRA to supply the Oncaspar product in Irish Packaging.

The approval, granted by the MHRA only impacts on the supply of product to England, Wales, and Scotland.

If you receive this letter and are located in Northern Ireland, please disregard the information since the derogation does not apply.

The DHPC issued in December 2023 is attached in Appendix 1 for convenience.

Yours faithfully,

Florent TEXIER
Managing Director

Annex 1

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Oncaspar 750 U/ml powder for solution for injection/infusion
Interim Supply of GB pack from batch 2239M with outdated packaging to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Servier Laboratories Limited is currently experiencing supply disruption with ONCASPAR 750 U/ml powder for solution for injection/infusion (pegaspargase) in Great Britain.

To ensure continuity in supply, Servier Laboratories Ltd has obtained approval from the MHRA to supply Oncaspar 750 U/ml powder for solution for injection/infusion product from the batch 2239M (expiry date 06/2025) as the carton and package leaflet of the batch do not reflect the currently approved information. The batch is expected to be on the GB market from approximately January 2024 and is anticipated to be on the market for approximately 5 weeks.

Please note the following:

- The product from the batch 2239M has the same formulation as the GB product.
- The product from the batch 2239M is manufactured according to the same manufacturing process and quality controls as the UK(GB) product.
- There are minor differences between the packaging of the batch 2239M, and UK(GB) packaging currently approved for the market. These differences are detailed below. Please ensure the UK(GB) Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed:

	UK – Batch 2239M	**UK – Approved mock-ups**
Carton	EU/1/15/1070/002	PLGB 05815/0114
Leaflet	**Section 2 What you need to know before you are given Oncaspar /…/**	**Section 2 What you need to know before you are given Oncaspar /…/**

Sefton House, Sefton Park, Bells Hill, Stoke Poges, Slough SL2 4JS - T. : +44 (0)1753 662744 - www.servier.co.uk
Registered in England No. 783023 – Registered Office as above

	Warnings and precautions /…/ This medicine can lead to fluctuations in clotting factors and may increase the risk of bleeding and/or clotting. If you are the parent of a child being treated with Oncaspar, tell the doctor if any of the above conditions apply to your child. /…/ Other medicines and Oncaspar Tell your doctor if you are using, have recently used or might use any other medicines This is important as Oncaspar may increase the side effects of other medicines through its effect on the liver which plays an important role in removing medicines from the body. In addition, it is especially important to tell your doctor if you are also using any of the following medicines: -/…/ - prednisone, a steroid medicine. If used at the same time as Oncaspar, the effects on the clotting ability of your blood are increased. - cytarabine, a medicine which can be used in cancer treatment, and could interfere with the effects of Oncaspar.	**Warnings and precautions** /…/ This medicine can lead to fluctuations in clotting factors and may increase the risk of bleeding and/or clotting. A side effect called osteonecrosis (bone damage) has been reported in the post-marketing setting in children and adolescents receiving Oncaspar (higher incidence seen in girls), especially when taken concomitantly with glucocorticoids (e.g. dexamethasone). If you are the parent of a child being treated with Oncaspar, tell the doctor if any of the above conditions apply to your child. /…/ Other medicines and Oncaspar Tell your doctor if you are using, have recently used or might use any other medicines This is important as Oncaspar may increase the side effects of other medicines through its effect on the liver which plays an important role in removing medicines from the body. In addition, it is especially important to tell your doctor if you are also using any of the following medicines: -/…/ - prednisone, a steroid medicine. If used at the same time as Oncaspar, the effects on the clotting ability of your blood are increased. - glucocorticoids when taken at the same time as part of the recommended leukaemia treatment, Oncaspar may increase the risk of steroid-induced osteonecrosis (bone damage) in children and adolescents, with a higher incidence seen in girls. Therefore, if you experience any new bone pain (i.e. pain in hip, knee or back), please inform your doctor as soon as possible. - cytarabine, a medicine which can be used in cancer treatment, and could interfere with the effects of Oncaspar.
	Section 3 How Oncaspar is given Your treatment with Oncaspar has been prescribed by a doctor experienced in medicines used to treat cancer. Your doctor will decide what dose of the medicine is needed and how often, based on your age and body surface area which is calculated from your height and weight.	**Section 3 How Oncaspar is given** Before administration, you might receive combination of medicines to help reduce your chances of getting allergic reactions. Your doctor will decide whether such premedication is necessary. Your treatment with Oncaspar has been prescribed by a doctor experienced in medicines used to treat cancer. Your doctor will decide what dose of the medicine is needed

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	The medicine is given as a solution by injection into a muscle or, if more suitable, into a vein.	and how often, based on your age and body surface area which is calculated from your height and weight. The medicine is given as a solution by injection into a muscle or, if more suitable, into a vein.
	Section 4 /…/ **Possible side effects** /…/ Not known (frequency cannot be estimated from the available data) - Severe skin reaction called toxic epidermal necrolysis; - Loss of kidney function (e.g., change in urine output, swelling of feet and ankles); - Stroke; - Severe allergic reaction that may cause loss of consciousness and could be life-threatening (anaphylactic shock); /…/	**Section 4** /…/ **Possible side effects** /…/ Not known (frequency cannot be estimated from the available data) - Severe skin reaction called toxic epidermal necrolysis; - Loss of kidney function (e.g., change in urine output, swelling of feet and ankles); - Stroke; - Severe allergic reaction that may cause loss of consciousness and could be life-threatening (anaphylactic shock); - Bone damage (osteonecrosis). /…/
	This leaflet was last revised in 11/2020	This leaflet was last revised in 10/2022
Labelling	No differences	No differences

- Please see below a mock-up of the packs from the batch 2239M that will be provided

- This DHPC will be supplied with each UK(GB) order of the batch 2239M.
- Oncaspar is indicated as a component of antineoplastic combination therapy in acute lymphoblastic leukaemia (ALL) in paediatric patients from birth to 18 years, and adult patients.
- 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 Oncaspar 750 U/ml powder for solution for injection/infusion is available via The Electronic Medicines Compendium at [Oncaspar 750 U/ml powder for solution for injection/infusion - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)]

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- For additional copies of the leaflet, please refer to Oncaspar 750 U/ml powder for solution for injection/infusion - Patient Information Leaflet (PIL) - (emc) (medicines.org.uk) 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 Oncaspar 750 U/ml powder for solution for injection/infusion.

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 Oncaspar 750 U/ml powder for solution for injection/infusion, please contact Servier Laboratories Limited Medical Information by

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

Florent TEXIER
Managing Director

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