

Direct Healthcare Professional Communication on the use of Irish packs of ▼Oncaspar (pegaspargase) in the UK

Dear Healthcare Professional,

The information in this letter has been agreed between Servier and the Medicines and Healthcare products Regulatory Agency (MHRA).

Summary

Oncaspar 750 U/ml solution for injection/infusion (pegaspargase) will be available on the UK market in Irish packaging from July 2019 to October 2019 (due to supply issues with the UK packaging). There is no difference to the product inside the pack.

Key messages for:

Pharmacists and Healthcare Professionals involved in the preparation of the infusion bags:

- The differences between the Irish and UK packaging are listed below:

	Ireland	UK
Carton	Ireland POM EAN Code: 3 664898 060132	United Kingdom POM EAN Code: 3 664898 060385
Patient Information Leaflet	Reporting of side effects You can also report side effects directly via the national reporting system listed below: Ireland HPRA Pharmacovigilance Earlsfort Terrace IRL - Dublin 2 Tel: +353 1 6764971 Fax: +353 1 6762517 Website: www.hpra.ie e-mail: medsafety@hpra.ie	Reporting of side effects 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.
	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)1 753 666409
Label	No differences	No differences

- The mock-up of the Irish carton is attached and highlights the differences between UK and Irish cartons.
- Please ensure that any Pharmacovigilance Information or medical enquiries for a UK patient are reported through the MHRA yellow card or directly to Servier Laboratories Ltd. (see «Call for reporting» and «Communication Information» below).
- The Irish cartons will meet serialisation requirements. The Global Trade Item Number (GTIN) of the Irish packs to be placed on the UK market, will be uploaded into the EU Hub and in turn diffused to the UK National Database. Therefore, no error message will appear when the Irish packs will be scanned for decommissioning at UK hospital level.

Prescribers

The product in the pack has not changed; there should be no effect on prescribing.

Further information on Oncaspar

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. Oncaspar is authorised for use in the European Union.

Product Information for Oncaspar (pegaspargase) is available either via The European Medicines Agency website at <https://www.ema.europa.eu/en/medicines/human/EPAR/oncaspar> or via the Electronic Medicines Compendium at <https://www.medicines.org.uk/emc/product/9307>.

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme. Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

It is easiest and quickest to report ADRs online via the Yellow Card website - <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store.

Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gsi.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- or by downloading and printing a form

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

Adverse events should also be reported to Servier Laboratories Limited Medical Information (Contact details below).

Communication information

For further inquiries concerning this information or any other questions, please contact Servier Medical Information in the UK

Tel: 01753 666409

Email: Medical.Information-UK@Servier.com

Yours faithfully,



François Druguet
Chief Executive Officer

Please note Servier Laboratories Ltd will collect and process your personal information for the purposes of Regulatory activities. For further information on our use of your personal information, please see the Privacy Notice available on our website: www.servier.co.uk/content/privacy-notices.

Job Bag UK19MDA0069

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Oncaspar - Irish carton – Mock up

