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2017/12/19

NOTICE OF SPECIAL HANDLING INSTRUCTIONS
VIALS of ERWINASE[®] from BATCH 185G* should be used with a 5-micron filter needle

Dear Healthcare Professional

Jazz Pharmaceuticals France SAS would like to inform you of the following:

Summary

- Small amounts of particulate matter have been observed bound to the stopper and/or present on the lyophilized cake of some vials of ERWINASE from BATCH 185G
- Vials of ERWINASE with visible particulate matter must not be administered. Please notify and retain the vial for collection. Follow all the recommended steps for the reconstitution of ERWINASE in accordance with the Canadian Product Monograph
- Carefully inspect the reconstituted product. If you discover particulate matter after reconstitution, do not administer the product and retain for collection.
- If there is no visible particulate matter after reconstitution, **use a standard 5-micron filter needle to withdraw the reconstituted product from the vial prior to administration as an additional precaution.**
- Vials from BATCH 185G can be identified by the following label, attached to the carton:

USE 5 MICRON FILTER NEEDLE
SEE NOTICE OF SPECIAL INSTRUCTIONS

Recommendations for Preparation

ERWINASE is used in combination with other anti-neoplastic agents to treat acute lymphoblastic leukaemia. It may also be used in other neoplastic conditions where depletion of asparagine might be expected to have a useful effect. Patients receiving treatment with L-asparaginase from *Escherichia coli* and who develop hypersensitivity to that enzyme may be able to continue treatment with ERWINASE as the enzymes are immunologically distinct.

During routine inspection of BATCH 185G, particulate matter was observed bound to the stopper and/or present on the lyophilized cake of some vials of ERWINASE. These affected vials were segregated. There is a possibility that some remaining vials may contain particulate matter bound to the stopper and/or on the lyophilized cake, which if transferred to reconstituted ERWINASE, may pose a safety risk to patients. In the event that you discover particulate matter, pre- or post- reconstitution, please notify the Customer Services department and retain the vial for collection.

In order to minimise the potential risk of exposure to sub-visible particulate matter, **use a standard 5-micron filter needle to withdraw the reconstituted product from the vial prior to administration as an additional precaution.** A study has demonstrated that filtration through a 5-micron filter needle after reconstitution has no effect on ERWINASE activity.

Jazz Pharmaceuticals has assessed the overall benefit to risk ratio of administering ERWINASE for the treatment of acute lymphoblastic leukaemia as positive, particularly with the additional precaution of using a 5-micron filter needle to withdraw the reconstituted product from the vial.

In the event that you should need to retain a vial of ERWINASE for collection, please contact the Canadian Distributor for replacement at 1-866-343-0344 (CGF Pharmatech).

In order to avoid a shortage, UK-Labelled vials from lot CAMR185G117 were imported in Canada. Similarly to the Canadian product, the contents of each vial of UK-labelled ERWINASE should be reconstituted in 1 to 2 mL of sodium chloride (0.9%) solution for injection as instructed in the Canadian Product Monograph.

Adverse Event Reporting

Any serious or unexpected side effects in patients receiving ERWINASE should be reported to Jazz Pharmaceuticals or Health Canada.

Jazz Pharmaceuticals
E-mail: AREporting@jazzpharma.com
Telephone: 1-800-520-5568 or 1-866-343-0344 (CGF Pharmatech)

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on [Adverse Reaction Reporting](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax.

For other health product inquiries related to this communication, contact Health Canada at:

Regulatory Operations and Regions Branch
E-mail: dcviu_uvcm@hc-sc.gc.ca
Telephone: 1-800-267-9675
Fax: 1-613-946-5636

Original signed by

A handwritten signature in black ink, appearing to be 'Kelvin', written in a cursive style.

Dr Kelvin Tan
Vice President Medical Affairs
Jazz Pharmaceuticals