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14/09/2022

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Streptokinase 250,000 IU and 1,500,000 IU vials for injection: supply of non-serialised packs

Dear Healthcare Professional,

Summary:

To ensure continuity in supply, Karma-Medica GmbH has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply packs of Streptokinase 250,000 IU and 1,500,000 IU vials for injection that do not have serial numbers due to an error during package design. These packs will be distributed by Tetris Pharma Ltd on behalf of the MAH Karma-Medica GmbH, with affected batches listed below:

Product	Batch number	Exp. Date	Qty
Streptokinase 1,500,000 IU	050620/1E	May-23	2996
Streptokinase 250,000 IU	250220/1A	Jan-23	2970
Streptokinase 1,500,000 IU	170622/1B	May-25	1800
Streptokinase 250,000 IU	170622/3A	May-25	378

Please note the following:

- This product holds a UK Marketing Authorisation (MA) and complies with the terms of the MA except for the fact the outer carton does not show a serial number.
- The product quality is not affected, and this DHPC aims to reduce any potential confusion and reassure healthcare professionals dispensing or administering these medicines.

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

IBAN: DE 12 5335 0000 0015 0025 49 • BIC: HELADEF 1 MAR



Call for reporting

Healthcare professionals are asked to report suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://yellowcard.mhra.gov.uk/, 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 contacts point

If you have any questions about this letter or require more information about Streptokinase, please contact Tetris Pharma Ltd Medical Information at Tel: 0330 1359 433, Fax: 01908 533370, or email medinfo@tetrispharma.com,

Yours Faithfully

Klaus Wiegand

Managing Director

Karma-Medica GmbH

Klaus Liegand