

GlaxoSmithKline UK Limited

Stockley Park West

Uxbridge

Middlesex

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January 2018

Direct Healthcare Professional Communication

Relenza (zanamivir): supply of Taiwanese stock; give patients UK leaflet

Relenza 5mg/dose, inhalation powder, pre-dispensed.

PL 10949/0327

Batch: VF4B

Expiry: 29.10.2024

January 2018

Dear Healthcare Professional,

GSK are temporarily unable to supply UK packs of Relenza. With approval from the Medicines and Healthcare products Regulatory Authority (MHRA), we will supply Taiwanese stocks from January to February 2018. We anticipate UK packs of Relenza being available again in March 2018.

Key messages:

- Taiwanese packs of Relenza 5mg/dose inhalation powder will be provided to the UK market from January to February 2018.
- The Taiwanese product 'Relenza 5mg powder for oral inhalation' is manufactured to the same specifications as the UK product 'Relenza 5mg/dose, inhalation powder, pre-dispensed'.
- The Taiwanese pack of Relenza looks slightly different to the UK pack of Relenza. There are also differences in the text and language used in the content of the Taiwanese Carton and Patient Information Leaflet (PIL) compared with the UK Carton and PIL.
- The Taiwanese pack is shared with Australia, therefore the carton contains both Taiwanese and English language, and the address for GSK Australia.
- The MHRA has considered these differences and has authorised the release of this batch to maintain supply of Relenza, in the UK.
- Reassure patients about the legitimacy of the product in case of any concerns arising from the inclusion of non-English characters on the packaging, or the inclusion of a GSK Australia address on the packaging.

Please take note of the following information:

- Keep Relenza out of the sight and reach of children
 - Relenza contains lactose monohydrate (contains milk proteins).
 - Relenza is for oral inhalation use only.
 - The UK PIL will be rubber banded to each Taiwanese pack of Relenza. Please ensure that the patient is provided with this PIL.
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- Make all relevant staff and patients receiving a Taiwanese Relenza pack aware of the content of this letter and provide them with the UK PIL, which will be attached to the Taiwanese Relenza pack with a rubber band.

The Summary of Product Characteristics and Patient Information Leaflet for Relenza 5mg/dose inhalation powder is available at www.medicines.org.uk/emc.

The communication of this information has been agreed with the MHRA and the Department of Health.

Reporting of suspected adverse reactions

Adverse events should be reported. For the UK, reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441.

Communication information

If you have any questions, contact the Customer Contact Centre, GlaxoSmithKline, Stockley Park West, Uxbridge, Middlesex UB11 1BT; customercontactuk@gsk.com; Freephone: 0800 221441. For medical information enquiries please email ukmedinfo@gsk.com or call 0800 221 441 (option 4).

Yours sincerely,

Philip Cruz
GSK UK Vaccines Medical Director