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Direct HealthCare Professional Communication
Fluenz® Tetra nasal spray suspension, Influenza vaccine (live attenuated, nasal): supply of Great Britain-labelled stock in Northern Ireland

August 2021

Supply of Fluenz Tetra [Influenza Vaccine (live attenuated, nasal)] to Northern Ireland

In agreement with the Medicines and Healthcare products Regulatory Agency (MHRA), AstraZeneca will now supply Great Britain-labelled Fluenz Tetra nasal spray suspension, Influenza vaccine (live attenuated, nasal) stock to Northern Ireland, in addition to the usual Northern Ireland-labelled Fluenz Tetra stock.

This action was taken to ensure continuity of supply of Fluenz Tetra in Northern Ireland for the duration of the 2021/2022 vaccination programme. AstraZeneca can confirm that the product formulations between the Great Britain and Northern Ireland stock are identical and they are both indicated for the prophylaxis of influenza in children and adolescents from 24 months to less than 18 years of age. The Fluenz Tetra Northern Ireland Patient Information Leaflet (PIL) and Summary of Product Characteristics (SmPC) are available electronically at:

https://www.emcmedicines.com/en-gb/northernireland/medicine?id=8e0d8d94-c0ec-40a3-8b9e-1f315f16edd2&type=smpc

Please note that some minor differences do exist between the Northern Ireland PIL and the Great Britain PIL that will be supplied with the pack. The differences are detailed as follows:

- The Yellow Card Scheme reporting details for Great Britain and Northern Ireland are the same. However the Northern Ireland leaflet also includes reporting details for Ireland and Malta.

- The Marketing Authorisation Holder and Manufacturer in the Great Britain PIL differs from that in the Northern Ireland PIL.

- The Great Britain PIL does not contain the contact details of the local representative of the Marketing Authorisation Holder. These details are included in the Northern Ireland PIL and are as follows:

Registered Office:
1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge
CB2 0AA
Registered Number: 03674842

United Kingdom (Northern Ireland), AstraZeneca UK Ltd
Tel: +44 1582 836 836

- The Great Britain PIL includes information on the Royal National Institute of the Blind (RNIB) service which provides an alternative version of the statutory information for patients in Great Britain. This information is not present in the Northern Ireland PIL, however, the RNIB service is available to all UK patients.

  Available options for Northern Ireland patients:
  - Contact the local representative on 01582 836 836 to request assistance with the RNIB services.
  - Contact the RNIB service directly on 0800 198 5000.

There are also minor differences on the Great Britain and Northern Ireland carton and label. The key differences are as follows:

- **Carton:** The Name and Address of the Marketing Authorisation Holder and Marketing Authorisation Numbers differ.

- **Label:** The Great Britain pack is supplied with a one-part label and the Northern Ireland pack is supplied with a three-part label.

Call for reporting
Healthcare professionals are asked to report any 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, treatment dates and product brand name.

If you have any queries regarding this product or information in this letter, please contact AstraZeneca Medical Information on 0800 783 0033.

Yours sincerely,

Dr Alexander de Giorgio-Miller
Country Medical Director
Vice President, AstraZeneca UK

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