VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA

Vifor Fresenius Medical Care Renal Pharma UK Ltd
2nd Floor, Waterfront, Lotus Park, The Causeway,
Staines-upon-Thames, Surrey, TW18 3AG, UK

Date: January 18th, 2024.

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Veltassa 16.8 g powder for oral suspension (*Patiromer*)

Interim Supply of COUNTRY Northern Ireland Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Vifor Fresenius Medical Care Renal Pharma France is currently experiencing improper labelling display on the outer packaging in Northern Ireland for the above-mentioned product.

To ensure continuity of supply, Vifor Fresenius Medical Care Renal Pharma France, Marketing Authorisation Holder of the above-mentioned products, has obtained approval from the MHRA to supply EU labelled products to be on the United Kingdom (Northern Ireland) market until end of April 2024.

- Veltassa 16.8 g powder for oral suspension (*Patiromer*):
    - Batch number 221268; Available stock: 48 packs

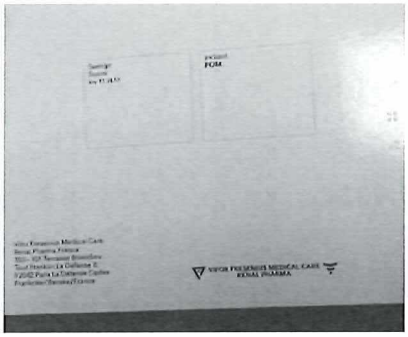
Please note the following:

- This product is licensed in the United Kingdom (Northern Ireland).
- This product supplied from EU countries has the same formulation, manufacturing process and quality control as the United Kingdom (Northern Ireland) products.
- The difference is related to the blue box information on the outer packaging where "Ireland" is displayed and United Kingdom (Northern Ireland) is missing.
- The MHRA has agreed to an exemption according to Article 63(3) of Council Directive 2001/83/EC, from the obligation that certain particulars should appear on the outer and immediate packaging of the above-mentioned product.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

Vifor Fresenius Medical Care Renal Pharma France
100-101 terrasse Boieldieu, Tour Franklin, La Défense 8, 92042 Paris La Défense Cedex.

- Veltassa 16.8 g powder for oral suspension (*Patiromer*)



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 ▼

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Company contacts point:

If you have any questions about this letter or require more information about the above-mentioned product, please contact Vifor Fresenius Medical Care Renal Pharma UK Ltd., at Second Floor, Waterfront, Kingsbury Crescent, Staines-upon-Thames, TW18 3BA, United Kingdom or via telephone at **+44 1276 853633** or via email at: **MedicalInfo_UK@viforpharma.com**

Yours faithfully,

Dr Hamdaoui
Head of Quality Management Services
Vifor Fresenius Medical Care Renal Pharma France

Vifor Fresenius Medical Care Renal Pharma France
100-101 terrasse Boieldieu, Tour Franklin, La Défense 8, 92042 Paris La Défense Cedex.