Proveca Pharma Ltd.
2 Dublin Landings
North Wall Quay
Dublin 1
Ireland

Tel: +353 1 513 6233

Date: 28th October 2022

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Sialanar 320 mcg/ml oral solution (Glycopyrronium): Interim Supply of Ireland / Germany/ Austria Labelled Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary:

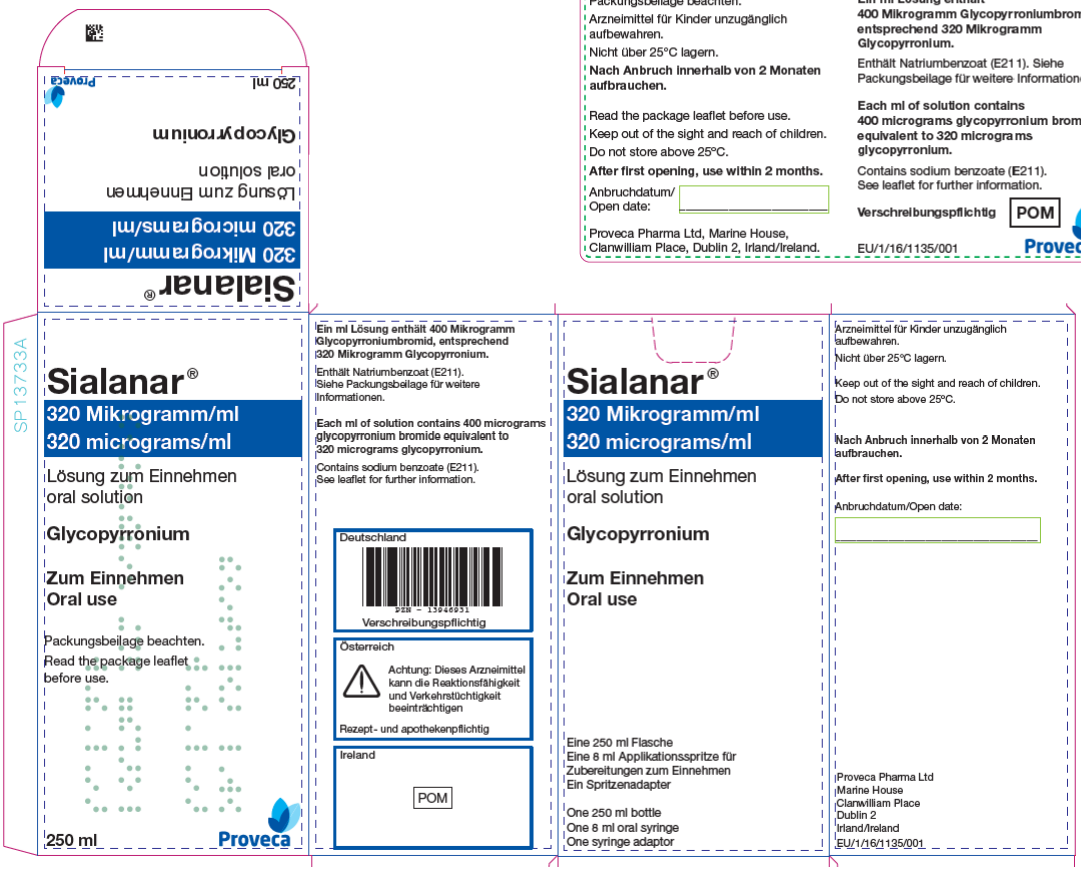
To ensure continuity in supply, Proveca Pharma Limited has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply Ireland / Germany / Austria labelled packs of Sialanar 320 mcg/ml oral solution (Glycopyrronium) in the UK (Great Britain) (250ml / 60ml).

Please note the following:

- The Ireland /Germany / Austria labelled packs contain all the same UK information, in English, with the addition of German language (250ml - ULM lots 5 and 6: 5,040 units. 60ml - ULM lot 9: 4,780 units).
- We expect these packs to be on the UK (Great Britain) market from 15 November 2022 until March 2023.
- This product is considered licensed in the UK.
- The product from Ireland / Germany / Austria has the same formulation as the UK (Great Britain) product.
- The product from Ireland / Germany / Austria is manufactured according to the same manufacturing process and quality controls as the UK (Great Britain) product.
- Please refer to the UK approved PIL supplied in the plastic bag alongside the Ireland / Germany / Austria packs, as this contains the MHRA Yellow Card reporting requirements. Discard the PIL within the box.
- Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed.
- The MHRA has agreed to an exemption granted in accordance with regulation 266(4)(a) and (b) of the Human Medicines Regulations (HMR) 2012.

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

Ireland / Germany / Austria carton



Ireland / Germany / Austria bottle label

Note: example shows 250ml pack labelling. The exemption will also be for the 60ml packs.

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 timing, treatment dates, and product brand name.

Company contact point

If you have any questions about this letter or require more information about Sialanar, please contact Proveca Medical Information at Medinfo@Proveca.com or telephone 0161 4682627.

Yours faithfully,

Robert Holmes
UK Country Manager
Proveca Pharma Limited