Date: 08 April 2024

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Lanreotide ADVANZ PHARMA 120 mg solution for injection in pre-filled syringe (Lanreotide acetate)

Interim Supply of German Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Advanz Pharma Limited is currently experiencing supply disruption with Lanreotide ADVANZ PHARMA 120 mg solution for injection in pre-filled syringe (Lanreotide acetate) in the UK.

To ensure continuity in supply, Advanz Pharma Limited has obtained approval from the Medicines and Healthcare products Regulatory Agency to supply German product (batch number 302003IR1; 659 packs) repacked with UK approved carton and Patient Information Leaflet, which is expected to be on the UK market from 08 April 2024 to 19 April 2024.

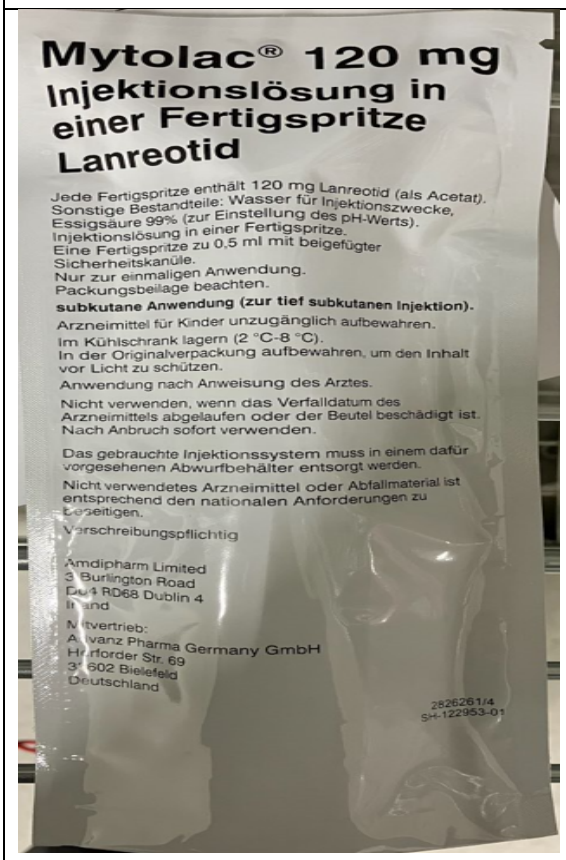
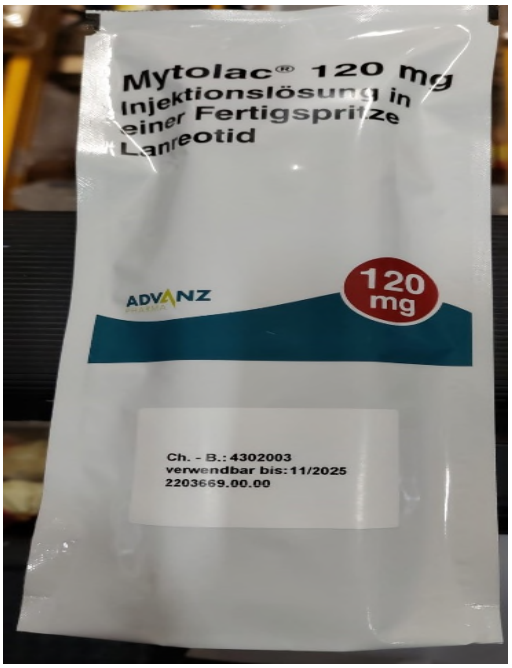
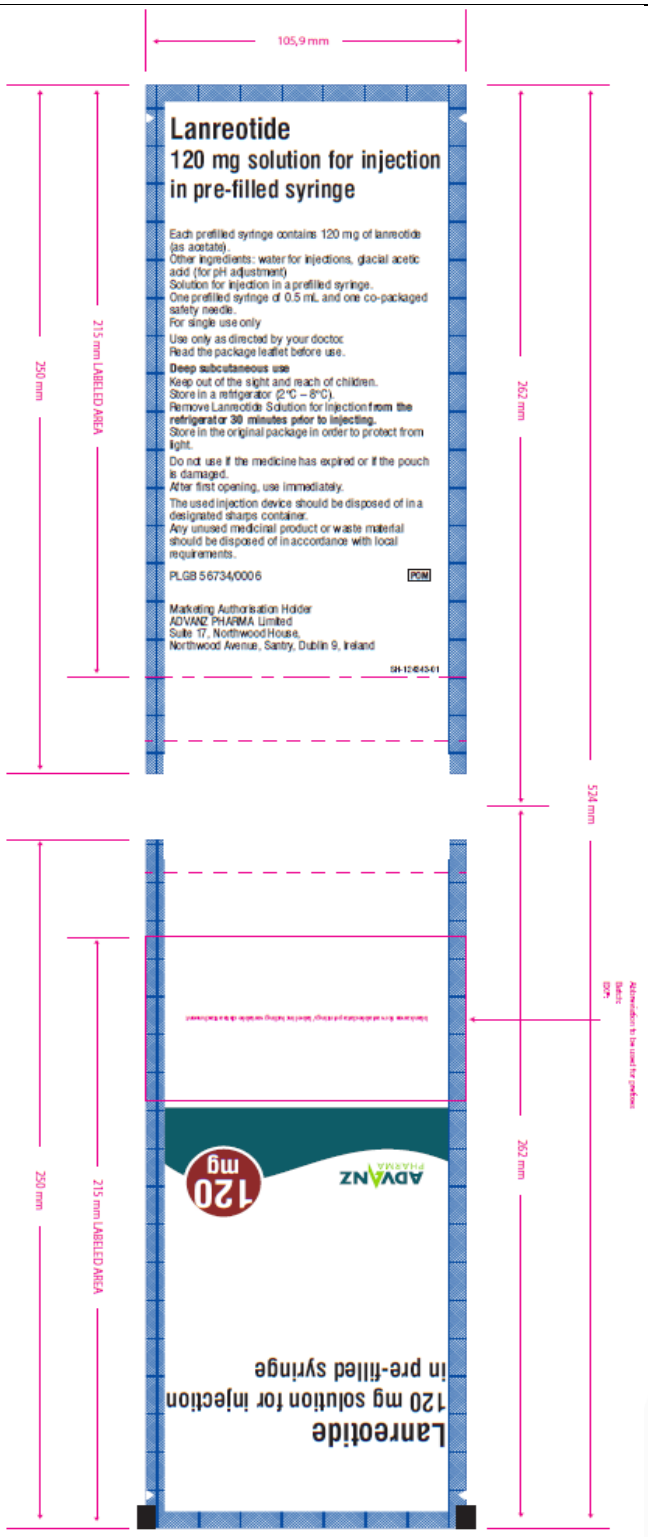
Please note the following:

- This product is considered licensed in the UK.
- The product from Germany i.e **Mytolac® 120 mg Injektionslösung in einer Fertigspritze, MA Number Zul. -Nr. 2203669.00.00** has the same formulation as the UK product.
- The product from Germany is manufactured according to the same manufacturing process and quality controls as the UK product.
- There are minor differences between the German and UK product information. Key differences are the product brand name and name of Marketing Authorisation Holder. There is one additional statement "Remove Lanreotide Solution for Injection from the refrigerator 30 minutes prior to injecting" which is not mentioned on the German pouch. All other information is same as the UK approved product information. We have included the German product pack shots along with UK approved product information for easy reference. Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed.
- Please refer to the UK approved PIL supplied with the German packs.
- For additional copies of the leaflet, please refer to https://www.medicines.org.uk/emc/ or contact the company contact point (see below).
- The MHRA has approved this product under a batch specific variation to the marketing authorisation.

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

ADVANZ PHARMA Limited / Suite 17 / Northwood House / Northwood Avenue / Santry / Dublin 9 / Ireland
T: +353 (0) 1 697 1640 / F: +353 (0) 1 697 1641 / enquiries@advanzpharma.com / www.advanzpharma.com
Company No: 43819

Images of imported product if labelling differs from standard UK product

German Pouch Label pack shot	*Current registered UK approved Pouch*
 	

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 contact point
If you have any questions about this letter or wish more information about Lanreotide ADVANZ PHARMA 120 mg solution for injection in pre- filled syringe, please contact please contact Advanz Pharma Limited medical information at medicalinformation@advanzpharma.com or telephone +44(0) 0208 588 9131.