

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.

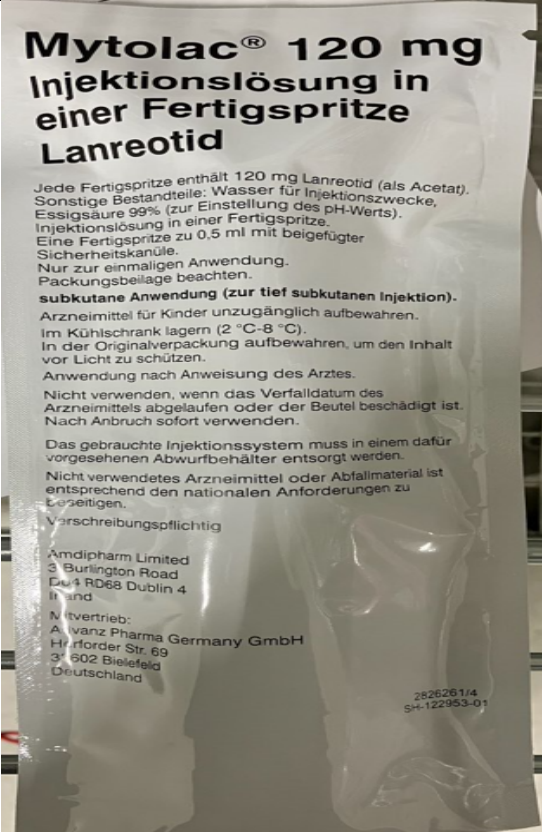
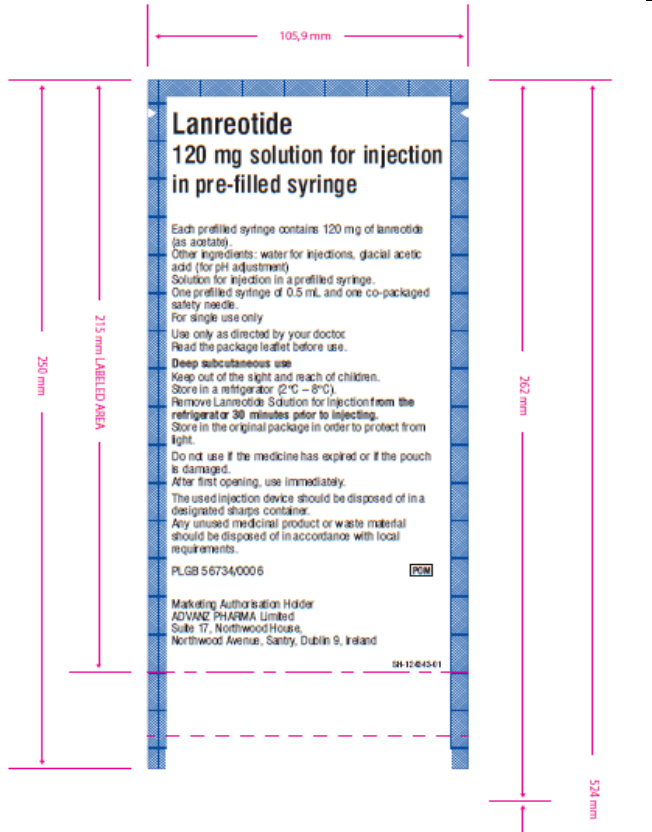

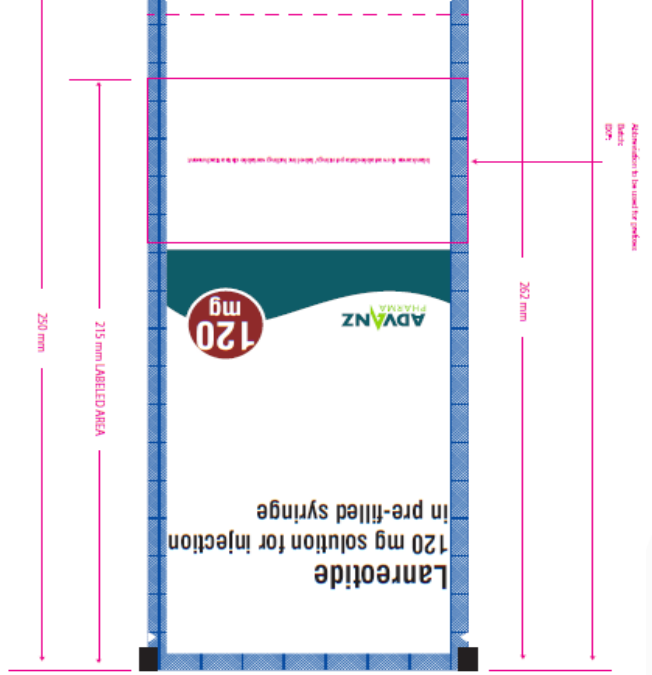
To ensure continuity in supply, Advanz Pharma Limited has obtained approval from the Medicines and Healthcare products Regulatory Agency to supply German product (batch number 302003IR1; 659 packs) repacked with UK approved carton and Patient Information Leaflet, which is expected to be on the UK market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

Images of imported product if labelling differs from standard UK product

German Pouch Label pack shot	Current registered UK approved Pouch
 <p>Mytolac® 120 mg Injektionslösung in einer Fertigspritze Lanreotid</p> <p>Jede Fertigspritze enthält 120 mg Lanreotid (als Acetat). Sonstige Bestandteile: Wasser für Injektionszwecke, Essigsäure 99% (zur Einstellung des pH-Werts). Injektionslösung in einer Fertigspritze. Eine Fertigspritze zu 0,5 ml mit beigefügter Sicherheitskanüle. Nur zur einmaligen Anwendung. Packungsbeilage beachten. subkutane Anwendung (zur tief subkutanen Injektion). Arzneimittel für Kinder unzugänglich aufbewahren. Im Kühlschrank lagern (2 °C-8 °C). In der Originalverpackung aufbewahren, um den Inhalt vor Licht zu schützen. Anwendung nach Anweisung des Arztes. Nicht verwenden, wenn das Verfalldatum des Arzneimittels abgelaufen oder der Beutel beschädigt ist. Nach Anbruch sofort verwenden.</p> <p>Das gebrauchte Injektionssystem muss in einem dafür vorgesehenen Abwurfbehälter entsorgt werden. Nicht verwendetes Arzneimittel oder Abfallmaterial ist entsprechend den nationalen Anforderungen zu entsorgen.</p> <p>Verschreibungspflichtig</p> <p>Amdipharm Limited 3 Burlington Road Du 4 RD68 Dublin 4 Irland</p> <p>Vertreib: Advanz Pharma Germany GmbH Harforder Str. 69 31602 Bielefeld Deutschland</p> <p>2826261/4 SH-122953-01</p>	 <p>Lanreotide 120 mg solution for injection in pre-filled syringe</p> <p>Each pre-filled syringe contains 120 mg of lanreotide (as acetate). Other ingredients: water for injections, glacial acetic acid (for pH adjustment) Solution for injection in a pre-filled syringe. One pre-filled syringe of 0.5 ml, and one co-packaged safety needle. For single use only Use only as directed by your doctor. Read the package leaflet before use.</p> <p>Deep subcutaneous use Keep out of the sight and reach of children. Store in a refrigerator (2°C – 8°C). Remove Lanreotide Solution for injection from the refrigerator 30 minutes prior to injecting. Store in the original package in order to protect from light. Do not use if the medicine has expired or if the pouch is damaged. After first opening, use immediately. The used injection device should be disposed of in a designated sharps container. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.</p> <p>PLGB 56734/0006 POM</p> <p>Marketing Authorisation Holder ADVANZ PHARMA Limited Suite 17, Northwood House, Northwood Avenue, Santry, Dublin 9, Ireland</p> <p>SH-12845-01</p> <p>Dimensions: 105,9 mm (width), 250 mm (height), 215 mm LABELLED AREA (width), 262 mm (height), 524 mm (total height).</p>
 <p>Mytolac® 120 mg Injektionslösung in einer Fertigspritze Lanreotid</p> <p>ADVANZ</p> <p>120 mg</p> <p>Ch. - B.: 4302003 verwendbar bis: 11/2025 2203669.00.00</p>	 <p>120 mg</p> <p>ADVANZ PHARMA</p> <p>Lanreotide 120 mg solution for injection in pre-filled syringe</p> <p>Dimensions: 250 mm (height), 215 mm LABELLED AREA (width), 262 mm (height), 524 mm (total height).</p>

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/SystemOne/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.