Medicines & Healthcare products Regulatory Agency

MHRA

Public Assessment Report

National Procedure

Lanreotide Advanz Pharma 60 mg, 90 mg and 120 mg solution for injection in a prefilled syringe

(lanreotide)

PLGB 56734/0004-0006

Advanz Pharma Limited

LAY SUMMARY

Lanreotide ADVANZ PHARMA 60 mg, 90 mg and 120 mg solution for injection in a prefilled syringe

(lanreotide)

This is a summary of the Public Assessment Report (PAR) for Lanreotide Advanz Pharma 60 mg, 90 mg and 120 mg solution for injection in a prefilled syringe. It explains how these products were assessed and their authorisation recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use these products.

These products will be referred to as Lanreotide solution for injection in this lay summary for ease of reading.

For practical information about using Lanreotide solution for injection, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What is Lanreotide solution for injection and what is it used for?
This product has been authorised by MHRA for Great Britain (GB; consisting of England, Scotland and Wales). This procedure takes into account the outcome of a decentralised (DC) procedures in European Union Member States (and/or Iceland, Liechtenstein, Norway) on 02 March 2021 (DK/H/3027/001-003/DC). This is known as the MR/DC Decision Reliance Procedure.

These applications are for generic medicines. This means that these medicines are the same as, and considered interchangeable with, reference medicines already authorised called Somatuline Autogel injection 60 mg, 90 mg and 120 mg solution for injection in a prefilled syringe.

Lanreotide solution for injection is used for:
- the treatment of acromegaly (a condition where the body produces too much growth hormone)
- the relief of symptoms such as flushing and diarrhoea that sometimes occur in patients with neuroendocrine tumours (NETs)
- the treatment and control of the growth of some advanced tumours of the intestine and pancreas called gastroenteropancreatic neuroendocrine tumours or GEP-NETs. It is used when these tumours cannot be removed by surgery.

How does Lanreotide solution for injection work?
Lanreotide solution for injection contains the active substance lanreotide, which belongs to a group of medicines called “Antigrowth hormones”. Lanreotide is similar to another substance (a hormone) called “somatostatin”. Lanreotide lowers the levels of hormones in the body such as growth hormone (GH), and insulin-like growth factor 1 (IGF-1) and inhibits the release of some hormones in the gastrointestinal tract and intestinal secretions. Additionally, it has an effect on some advanced type of tumours (called neuroendocrine tumours) of the intestine and pancreas by stopping or delaying their growth.

How is Lanreotide solution for injection used?
The pharmaceutical form of this medicine is solution for injection in a prefilled syringe.

Recommended dose

Treatment of acromegaly

The recommended dose is one injection every 28 days. The patient's doctor may adapt the dose of the patient's injection using one of the three available strengths of Lanreotide solution for injection (60 mg, 90 mg or 120 mg).

If the patient is well controlled on their treatment, their doctor can recommend a change in the frequency of their Lanreotide 120 mg injections to one injection every 42 or 56 days. Any change in dose will depend on the patient's symptoms and how they respond to the medicine.

The patient's doctor will also decide how long the patient should be treated for.

Relief of symptoms (such as flushing and diarrhoea) associated with neuroendocrine tumours

The recommended dose is one injection every 28 days. The patient's doctor may adapt the dose of the patient's injection using one of the three available strengths of Lanreotide solution for injection (60 mg, 90 mg or 120 mg).

If the patient is well-controlled on your treatment, their doctor can recommend a change in the frequency of their Lanreotide 120 mg injections to one injection every 42 or 56 days. The patient's doctor will also decide how long they should be treated for.

Treatment of advanced tumours of the intestine and pancreas called gastroenteropancreatic neuroendocrine tumours or GEP-NETs. Used when these tumours cannot be removed by surgery.

The recommended dose is 120 mg every 28 days. The patient's doctor will decide how long the patient should be treated with Lanreotide solution for injection for tumour control.

Method of administration

Lanreotide solution for injection should be administered by deep subcutaneous injection. If the injection is being given by a healthcare professional or someone else who has been trained (family member or friend), the injection will be given in the upper, outer external quadrant of the buttock.

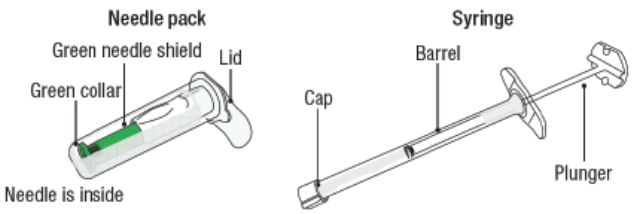
If the patient is injecting themselves after appropriate training, the injection should be given in the upper outer thigh.

The decision regarding self-administration or administration by another trained person should be taken by the patient's doctor.

INSTRUCTION FOR USE

A. What's in the box

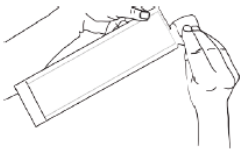
The following instructions explain how to inject Lanreotide Solution for Injection.
Please read all instructions carefully before starting the injection.



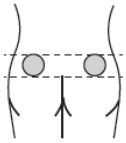
B. Before your start

B1. Remove Lanreotide Solution for Injection **from the refrigerator 30 minutes prior to injecting.** Injection of cold medication may be painful. Keep the laminated pouch sealed until just before the injection.

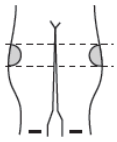
B2. Before opening the pouch, check that it is intact and that the medication has not expired. The expiry date is printed on the outer carton and the pouch - **Do not use if the medication has expired or if the pouch is damaged.**



B3. **Wash hands** with soap and dry hands thoroughly before starting.
B4. Make sure there is a clean surface for preparation.
B5. Choose injection site - the sites are shown below.
B6. Make sure to **clean the injection site**.
B7. Tear open the pouch and take out the pre-filled syringe.



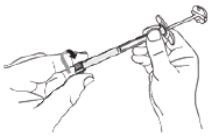
If you are injecting someone else: Inject into the upper outer area of the **buttock.**



If you are injecting yourself: Inject into the upper outer part of your **thigh.**

Alternate the injection site between the right and left side each time you have an injection of Lanreotide Solution for Injection.

C. Get the syringe ready

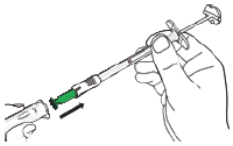


C1: Remove the cap from the syringe
- With one hand, hold the syringe barrel steady **(not the plunger)**.
- With the other hand, remove the cap by twisting it.

C2: Open the needle pack
- Hold the needle pack and pull the lid off.
- Caution: Do not touch the open end of the needle pack. This needs to stay clean.

C3: Put the end of the syringe into open end of the needle pack
- Hold the needle pack with one hand.
- With the other, hold the syringe barrel steady **(not the plunger)** and twist until the syringe and needle are fully locked together.
- **They are fully locked when you cannot turn it any further.**

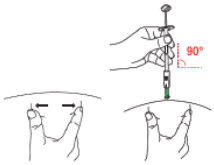
Important: Tight the syringe firmly to avoid drug leakage.



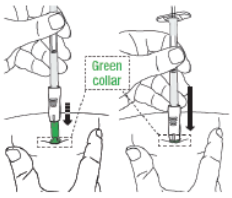
C4: Remove the needle from the pack
- Hold the syringe barrel **(not the plunger)**.
- Pull the needle straight out from the needle pack **without twisting or turning** to make sure that the syringe is well connected to the safety needle.

Caution: Partially exposed needle from this step onwards.

D. Perform injection

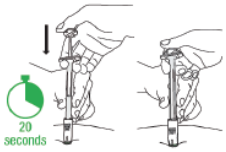


D1: Position the syringe
- To check which site you should use, refer to section B.
- Stretch the skin around the injection site flat and tight using your thumb and index finger.
- Hold the lower part of the syringe barrel **(not the plunger)** with your other hand.
- Position the syringe at a 90-degree angle to the skin.



D2: Insert the needle

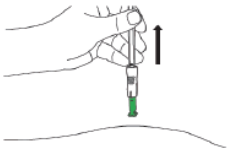
- Without folding or pressing on the skin at the injection site, push the needle firmly against the skin.
- The green safety shield will retract.
- **Keep going until only the green collar of the safety shield is visible.**
- **Do not** push the plunger in this step. Hold the syringe in this position for the next step.



D3: Push the top of the plunger

- Move your hand from the skin to the plunger.
- Push the plunger **slowly** until the top touches the syringe barrel (it is easier to depress the plunger with your dominant hand).
- This should take around 20 seconds.

E. Remove and throw away syringe



E1: Remove from the skin

- Lift the syringe straight up and away from your body.
- The green needle shield will cover the needle.

E2: Apply gentle pressure

- Apply gentle pressure to the injection site with a dry cotton ball or sterile gauze to prevent any bleeding.
- **Do not** rub or massage the injection site after administration.

E3: Throw away

- Dispose of the used syringe and needle according to your local laws and regulations or how your doctor has shown you.
- The needles are not reusable.
- **Do not** dispose of the syringe or needle in your general household rubbish.

For further information on how Lanreotide solution for injection is used, refer to the PIL and Summaries of Product Characteristics (SmPCs) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

These medicine can only be obtained with a prescription.

The patient should always take their medicine exactly as their doctor/pharmacist has told them. The patient should check with their doctor or pharmacist if they are not sure.

The patient should ask the administering healthcare practitioner if they have any questions concerning their medicine.

What benefits of Lanreotide solution for injection have been shown in studies?
As the applications for Lanreotide solution for injection are generic medicines, studies in healthy volunteers have been limited to tests to determine that they are bioequivalent to the reference medicines. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Lanreotide solution for injection?
As the applications for Lanreotide solution for injection are generic medicines and are bioequivalent to the reference medicines, their benefits and possible side effects are considered to be the same as the reference medicines.

For the full list of all side effects reported with these medicines, see Section 4 of the PIL or the SmPCs available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicines. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at https://yellowcard.mhra.gov.uk or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicines.

Why was Lanreotide solution for injection approved?
It was concluded that, the applications for Lanreotide solution for injection have been shown to be comparable to and to be bioequivalent to the reference medicines.

The MHRA decided that the benefits are greater than the risks and recommended that these medicines can be approved for use.

What measures are being taken to ensure the safe and effective use of Lanreotide solution for injection?
As for all newly-authorised medicines, a Risk Management Plan (RMP) has been developed for Lanreotide solution for injection. The RMP details the important risks of Lanreotide solution for injection, how these risks can be minimised, any uncertainties about Lanreotide solution for injection (missing information), and how more information will be obtained about the important risks and uncertainties.

The following safety concerns have been recognised for Lanreotide solution for injection:

Summary of safety concerns	
Important identified risks	• Gastrointestinal effects • Cholelithiasis • Effects on glycoregulation • Effects on thyroid function • Bradycardia • Administrative site reactions • Device Use Errors • Pancreatitis • Allergic reactions
Important potential risks	• Effects on bioavailability of concomitant medication • Hepatic dysfunction • Renal impairment
Missing information	• Pregnancy and lactation • Paediatric populations

The information included in the SmPCs and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Lanreotide solution for injection are continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with these applications and are satisfactory.

Other information about Lanreotide solution for injection
A Marketing Authorisation was granted in GB on 23 November 2022.

The full PAR for Lanreotide solution for injection follows this summary.

This summary was last updated in February 2023.

TABLE OF CONTENTS

I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the applications for Lanreotide Advanz Pharma 60 mg, 90 mg and 120 mg solution for injection in a prefilled syringe (PLGB 56734/0004-0006) could be approved.

The products are approved for the following indications:

- The treatment of individuals with acromegaly when the circulating levels of Growth Hormone (GH) and/or Insulin-like Growth Factor-1 (IGF-1) remain abnormal after surgery and/or radiotherapy, or in patients who otherwise require medical treatment.
- The treatment of grade 1 and a subset of grade 2 (Ki67 index up to 10%) gastroenteropancreatic neuroendocrine tumours (GEP-NETs) of midgut, pancreatic or unknown origin where hindgut sites of origin have been excluded**,** in adult patients with unresectable locally advanced or metastatic disease (see section 5.1 of the Summary of Product Characteristics (SmPC)).
- The treatment of symptoms associated with neuroendocrine (particularly carcinoid) tumours.

The active substance, lanreotide, is an octapeptide analogue of natural somatostatin. Like somatostatin, lanreotide is an inhibitor of various endocrine, neuroendocrine, exocrine and paracrine functions. Lanreotide has a high affinity for human somatostatin receptors (SSTR) 2 and 5, and a reduced binding affinity for human SSTR 1, 3 and 4. Activity at human SSTR 2 and 5 is the primary mechanism considered to be responsible for GH inhibition. Lanreotide is more active than natural somatostatin and shows a longer duration of action.

Lanreotide, like somatostatin, exhibits a general exocrine anti-secretory action. It inhibits the basal secretion of motilin, gastric inhibitory peptide and pancreatic polypeptide, but has no significant effect on fasting secretin or gastrin secretion. Additionally, it decreases the levels of plasma chromogranin A and urinary 5-HIAA (5 Hydroxyindolacetic acid) in patients with GEP-NETs and elevated levels of these tumour markers. Lanreotide markedly inhibits meal-induced increases in superior mesenteric artery blood flow and portal venous blood flow. Lanreotide significantly reduces prostaglandin E1-stimulated jejunal secretion of water, sodium, potassium and chloride. Lanreotide reduces prolactin levels in patients with acromegaly patients treated long term.

These products have been authorised by MHRA for Great Britain (GB; consisting of England, Scotland and Wales. This procedure takes into account the outcome of a decentralised (DC) procedure in European Union Member States (and/or Iceland, Liechtenstein, Norway) on 02 March 2021 (DK/H/3027/001-003/DC).

For the scientific discussion of the quality, non-clinical and clinical assessment conducted during the DC procedures, please refer to the Reference Member State (RMS) Public Assessment Report, available on the RMS regulatory agency website or on the Heads of Medicines Agencies website.

These applications were approved under Regulation 51B of the Human Medicines Regulation 2012, as amended (previously Article 10(1) of Directive 2001/83/EC, as amended) as generic medicines of suitable originator medicinal products, Somatuline Autogel injection 60 mg, 90 mg and 120 mg solution for injection in a prefilled syringe that have been licensed for a suitable time, in line with the legal requirements.

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for these products at all sites responsible for the manufacture, assembly and batch release of these products.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with these applications and are satisfactory.

Marketing Authorisations were granted on 23 November 2022.

II. PRODUCT INFORMATION

SUMMARY OF PRODUCT CHARACTERITICS (SmPC)

The SmPCs are in line with current guidelines and is satisfactory.

PATIENT INFORMATION LEAFLET (PIL)

The PIL is in line with current guidelines and is satisfactory.

LABEL

The labelling is in line with current guidelines and is satisfactory.

III. QUALITY ASPECTS

The MHRA considered that the quality data submitted for these applications is satisfactory.

The grant of Marketing Authorisations is recommended.

IV. NON-CLINICAL ASPECTS

The MHRA considered that the non-clinical data submitted for these applications is satisfactory.

The grant of Marketing Authorisations is recommended.

V. CLINICAL ASPECTS

The MHRA considered that the clinical data submitted for these applications is satisfactory.

The grant of Marketing Authorisations is recommended.

VI. RISK MANAGEMENT PLAN (RMP)

The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

VII. USER CONSULTATION

A full colour mock-up of the Patient Information Leaflet (PIL) has been provided with the applications, in accordance with legal requirements.

The PIL has been evaluated via a user consultation study in accordance with legal requirements. The results show that the PIL meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

VIII. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

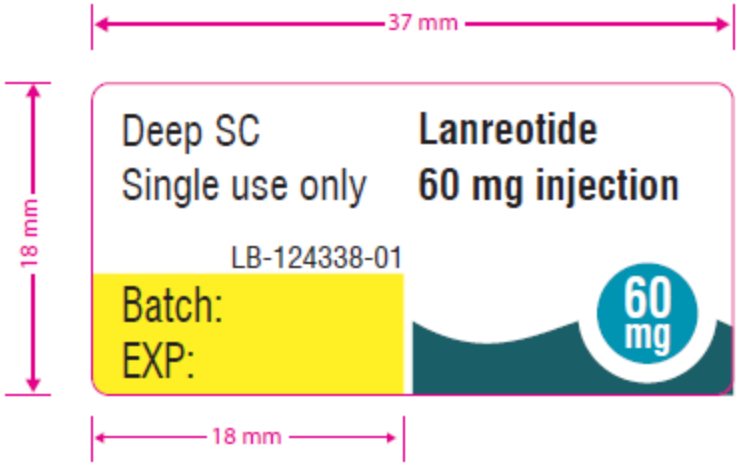
The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The benefit/risk balance is, therefore, considered to be positive.

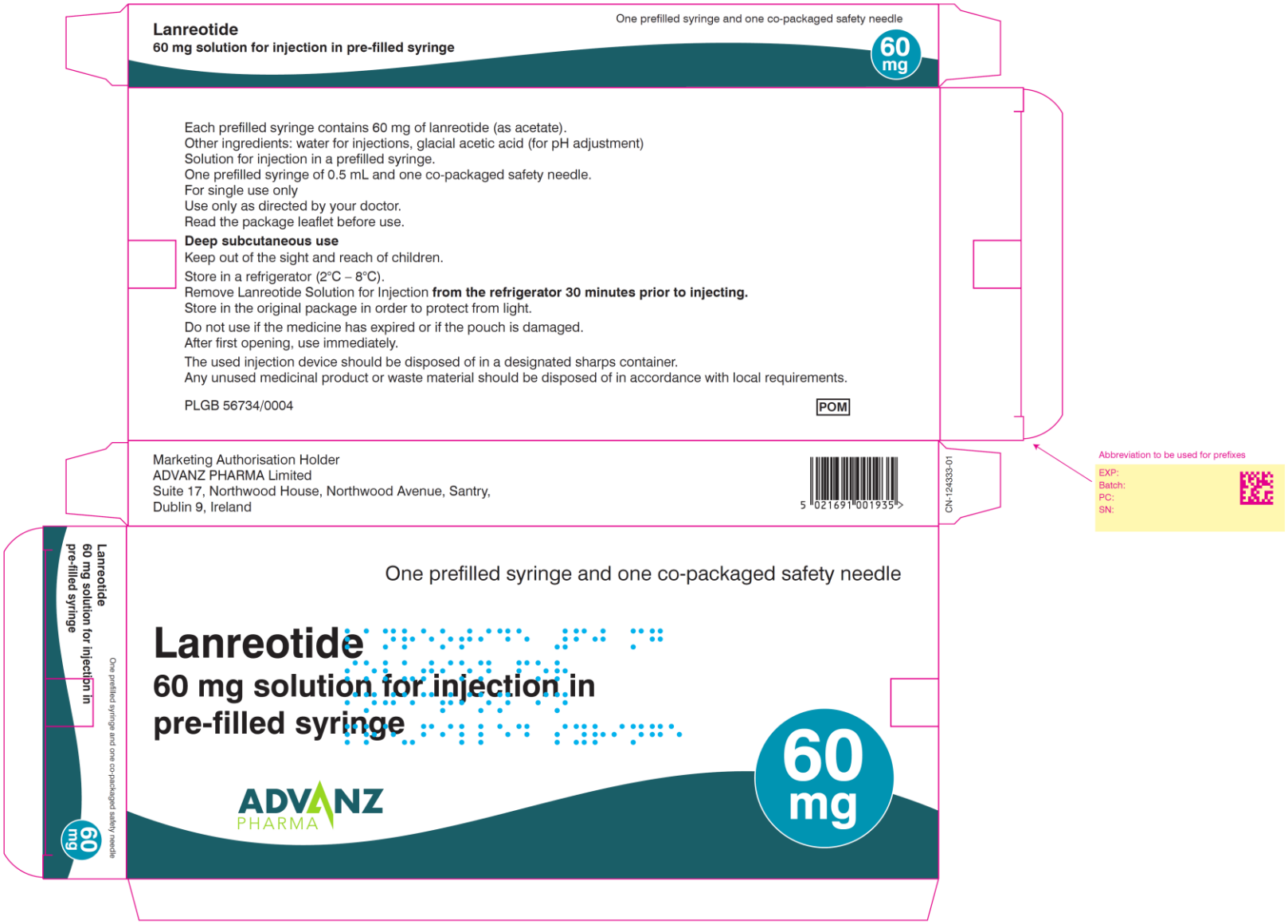
The SmPCs, PIL and labelling are satisfactory.

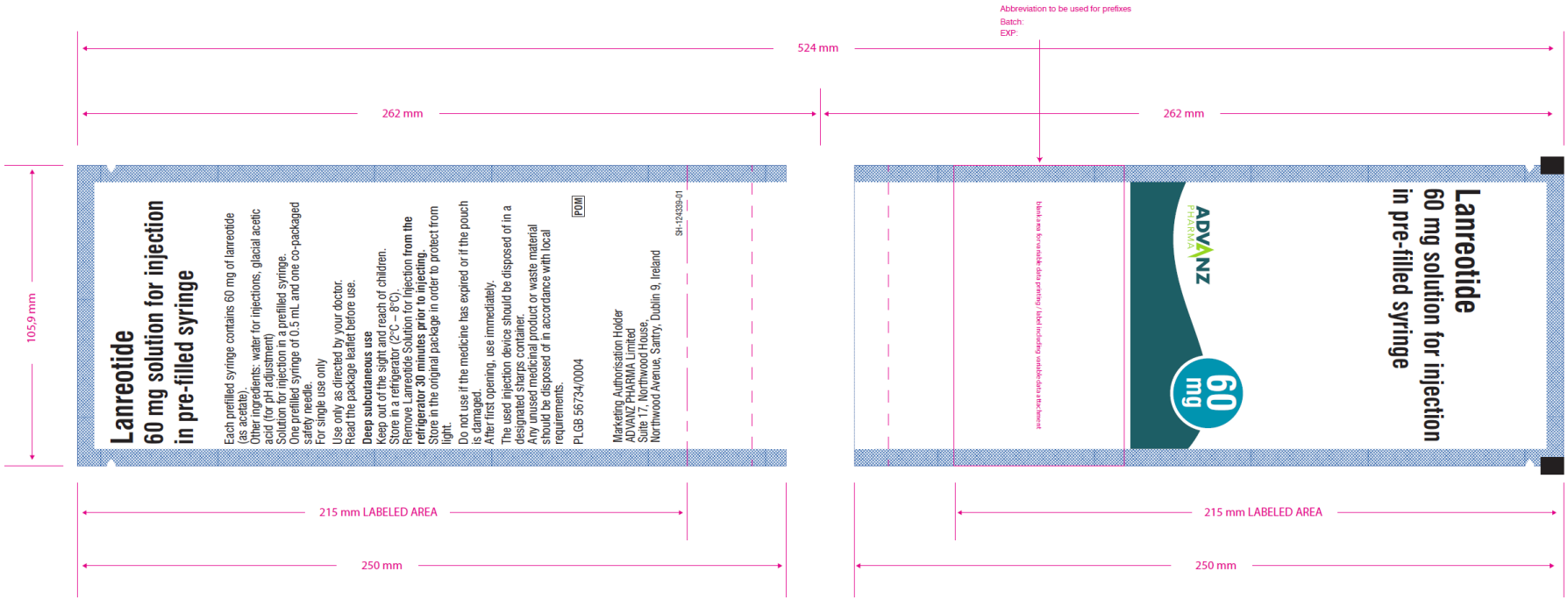
In accordance with legal requirements, the current approved UK versions of the SmPCs and PIL for these products are available on the MHRA website.

Representative copies of the labels at the time of GB licensing are provided below:

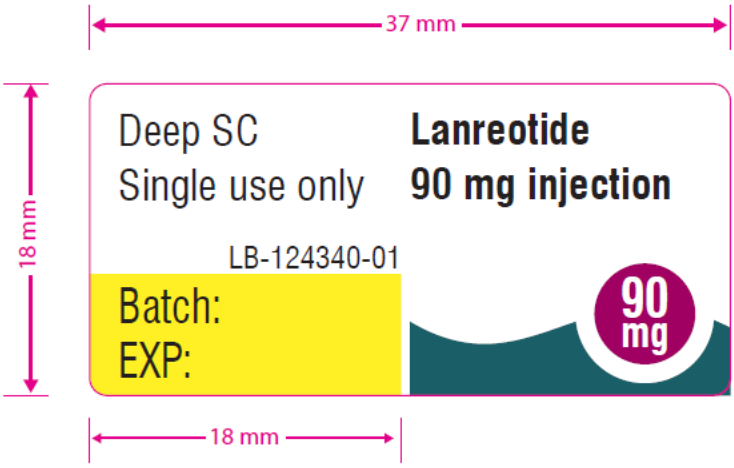
Lanreotide Advanz Pharma 60 mg solution for injection in a prefilled syringe

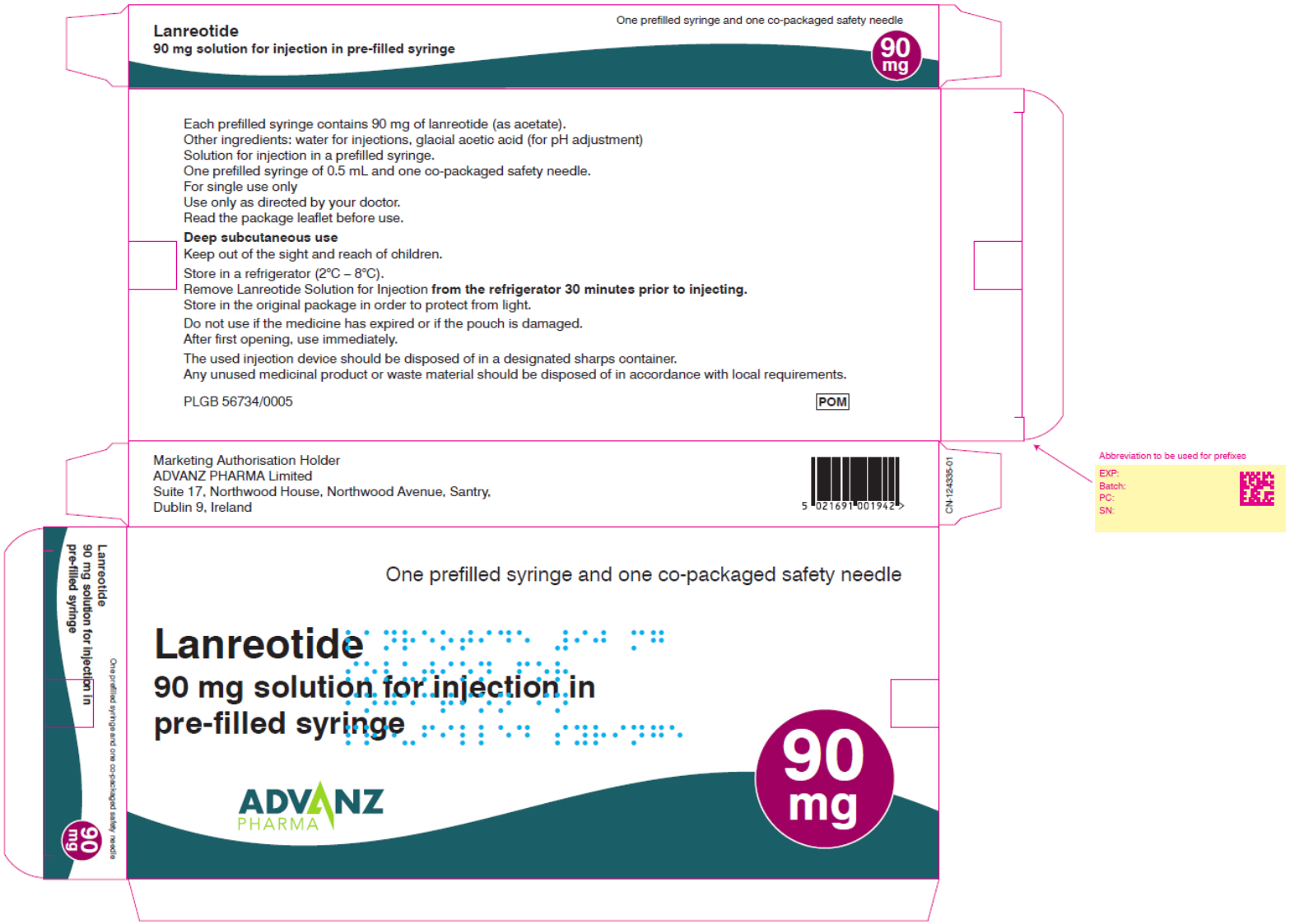


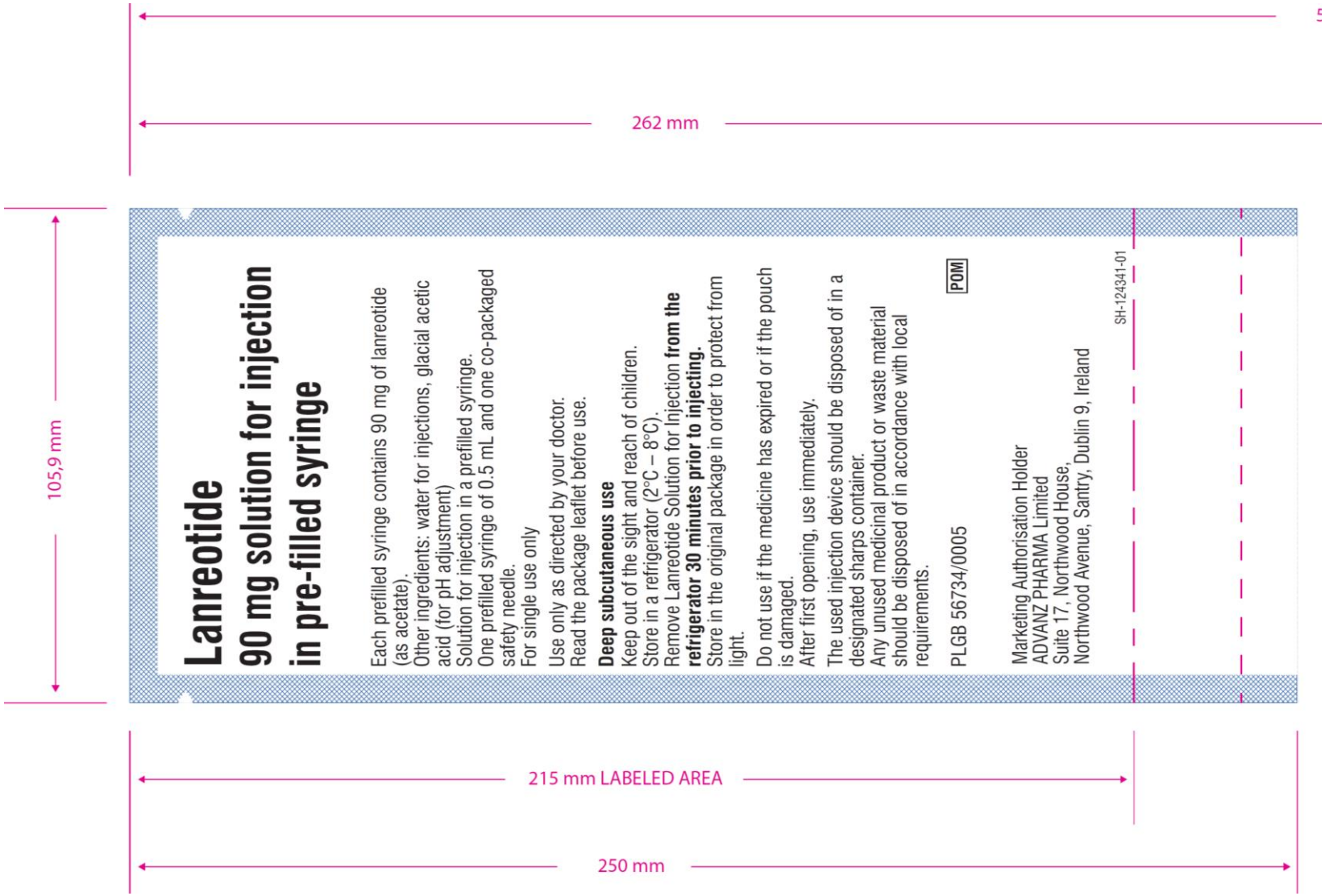

Lanreotide
60 mg solution for injection in pre-filled syringe
One prefilled syringe and one co-packaged safety needle
60 mg
Each prefilled syringe contains 60 mg of lanreotide (as acetate).
Other ingredients: water for injections, glacial acetic acid (for pH adjustment)
Solution for injection in a prefilled syringe.
One prefilled 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.
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.
PLGB 56734/0004
POM
Marketing Authorisation Holder
ADVANZ PHARMA Limited
Suite 17, Northwood House, Northwood Avenue, Santry,
Dublin 9, Ireland
5 021691 001935
CN-124333-01
Abbreviation to be used for prefixes
EXP:
Batch:
PC:
SN:
Lanreotide
60 mg solution for injection in pre-filled syringe
One prefilled syringe and one co-packaged safety needle
60 mg
One prefilled syringe and one co-packaged safety needle
Lanreotide
60 mg solution for injection in pre-filled syringe
ADVANZ PHARMA
60 mg


Abbreviation to be used for prefixes
Batch:
EXP:
524 mm
262 mm
262 mm
105,9 mm
Lanreotide
60 mg solution for injection
in pre-filled syringe
Each prefilled syringe contains 60 mg of lanreotide (as acetate).
Other ingredients: water for injections, glacial acetic acid (for pH adjustment)
Solution for injection in a prefilled syringe.
One prefilled 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.
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.
POM
PLGB 56734/0004
Marketing Authorisation Holder
ADVANZ PHARMA Limited
Suite 17, Northwood House,
Northwood Avenue, Santry, Dublin 9, Ireland
SH-124339-01
215 mm LABELED AREA
250 mm
blank area for machine data printing / label including serialisation attachment
ADVANZ PHARMA
60 mg
Lanreotide
60 mg solution for injection
in pre-filled syringe
215 mm LABELED AREA
250 mm

Lanreotide Advanz Pharma 90 mg solution for injection in a prefilled syringe




Lanreotide
90 mg solution for injection in pre-filled syringe
One prefilled syringe and one co-packaged safety needle
90 mg
Each prefilled syringe contains 90 mg of lanreotide (as acetate).
Other ingredients: water for injections, glacial acetic acid (for pH adjustment)
Solution for injection in a prefilled syringe.
One prefilled 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.
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.
PLGB 56734/0005
POM
Marketing Authorisation Holder
ADVANZ PHARMA Limited
Suite 17, Northwood House, Northwood Avenue, Santry,
Dublin 9, Ireland
5 021691 001942
CN-124335-01
Abbreviation to be used for prefixes
EXP:
Batch:
PC:
SN:
One prefilled syringe and one co-packaged safety needle
Lanreotide
90 mg solution for injection in pre-filled syringe
ADVANZ PHARMA
90 mg


262 mm
105,9 mm
Lanreotide
90 mg solution for injection
in pre-filled syringe
Each prefilled syringe contains 90 mg of lanreotide (as acetate).
Other ingredients: water for injections, glacial acetic acid (for pH adjustment)
Solution for injection in a prefilled syringe.
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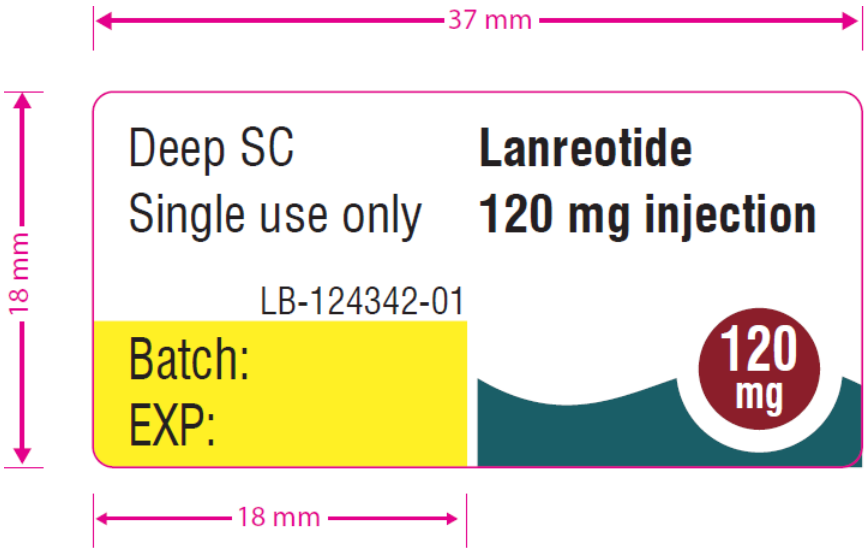
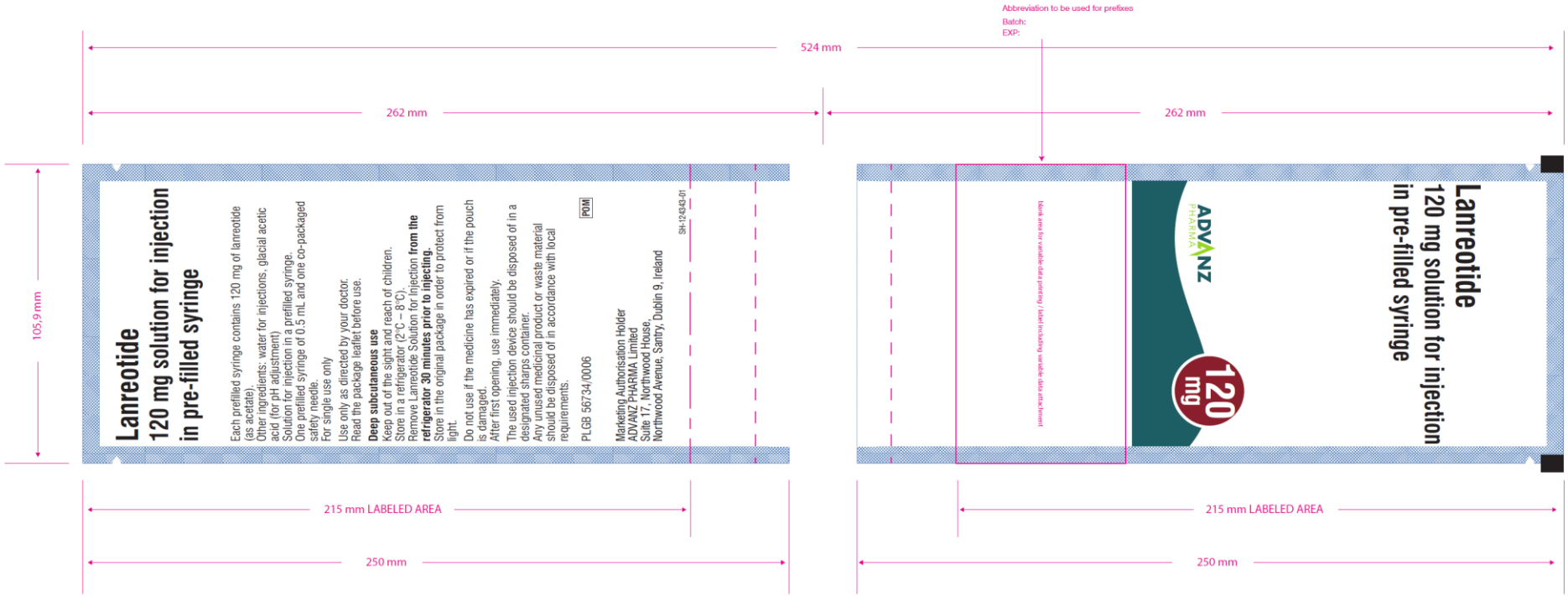
POM
PLGB 56734/0005
Marketing Authorisation Holder
ADVANZ PHARMA Limited
Suite 17, Northwood House,
Northwood Avenue, Santry, Dublin 9, Ireland
SH-124341-01
215 mm LABELED AREA
250 mm

Lanreotide Advanz Pharma 120 mg solution for injection in a prefilled syringe




Lanreotide
120 mg solution for injection in pre-filled syringe
One prefilled syringe and one co-packaged safety needle
120 mg
Each prefilled syringe contains 120 mg of lanreotide (as acetate).
Other ingredients: water for injections, glacial acetic acid (for pH adjustment)
Solution for injection in a prefilled syringe.
One prefilled 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.
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.
PLGB 56734/0006
POM
Marketing Authorisation Holder
ADVANZ PHARMA Limited
Suite 17, Northwood House, Northwood Avenue, Santry,
Dublin 9, Ireland
5 021691 001959
CN-124337-01
Abbreviation to be used for prefixes
EXP:
Batch:
PC:
SN:
Lanreotide
120 mg solution for injection in pre-filled syringe
One prefilled syringe and one co-packaged safety needle
120 mg
One prefilled syringe and one co-packaged safety needle
Lanreotide
120 mg solution for injection in pre-filled syringe
ADVANZ PHARMA
120 mg


Abbreviation to be used for prefixes
Batch:
EXP:
524 mm
262 mm
262 mm
105,9 mm
Lanreotide
120 mg solution for injection in pre-filled syringe
Each prefilled syringe contains 120 mg of lanreotide (as acetate).
Other ingredients: water for injections, glacial acetic acid (for pH adjustment)
Solution for injection in a prefilled syringe.
One prefilled 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.
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.
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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.
PLGB 56734/0006
POM
Marketing Authorisation Holder
ADVANZ PHARMA Limited
Suite 17, Northwood House,
Northwood Avenue, Santry, Dublin 9, Ireland
SH-12434-01
blank area for variable data printing / label including variable data attachment
ADVANZ PHARMA
120 mg
Lanreotide
120 mg solution for injection in pre-filled syringe
215 mm LABELED AREA
250 mm
215 mm LABELED AREA
250 mm

TABLE OF CONTENTS OF THE PAR UPDATE

Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations, where significant changes are made, are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPCs and/or PIL available on the MHRA website.

Application type	**Scope**	**Product information affected**	**Date of grant**	**Outcome**	**Assessment report attached Y/N**