B. PACKAGE LEAFLET

Package leaflet: Information for the user

Myrelez® 60 mg solution for injection in pre-filled syringe
Myrelez® 90 mg solution for injection in pre-filled syringe
Myrelez® 120 mg solution for injection in pre-filled syringe
Lanreotide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Myrelez® is and what it is used for

Myrelez® contains the active substance lanreotide, which belongs to a group of medicines called "Antigrowth hormones". It 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.

What Myrelez® is used for:
- The treatment of acromegaly (a condition where your 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.

2. What you need to know before you use Myrelez®

Do not use Myrelez®:
- if you are allergic to lanreotide, somatostatin or drugs from the same family (analogues of somatostatin) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Myrelez®:
- If you are **diabetic**, as Myrelez® may affect your blood sugar levels. Your doctor may check your blood sugar levels and possibly alter your anti-diabetic treatment while you are receiving Myrelez®

- If you have **gallstones**, as Myrelez® may lead to gallstone formation in the gallbladder. In this case, you may need to be monitored periodically. Your doctor may decide to stop treatment with lanreotide if complications arising from gallstones occur.
- If you have any **thyroid problems**, as Myrelez® may slightly decrease your thyroid function
- If you have **cardiac disorders**, as bradycardia (slower heart beat) may occur under Myrelez® treatment. Special care should be taken when initiating treatment with Myrelez® in patients with bradycardia.

If any of the above applies to you, talk to your doctor or pharmacist before using Myrelez®.

Children
Myrelez® is not recommended in children.

Other medicines and Myrelez®
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Special care should be taken in case of co-administration with:
- **Ciclosporin** (a drug reducing immune reactions e.g. after transplantation or in cases of autoimmune disease)
- **Bromocriptine** (dopamine agonist used in the treatment of certain types of tumours of the brain and Parkinson's disease, or to prevent lactation following childbirth)
- **Bradycardia inducing drugs** (drugs slowing the heart beat, e.g beta blockers).

Dose adjustments of such concomitant medications may be considered by your doctor.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
If so, Myrelez® should be given to you only if clearly needed.

Driving and using machines
Myrelez® is unlikely to affect your ability to drive or use machines, however possible side effects such as dizziness may occur with Myrelez®. If you are affected be careful when driving or using machinery.

3. How to use Myrelez®

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

<u>Recommended dose</u>

Treatment of acromegaly
The recommended dose is one injection every 28 days. Your doctor may adapt the dose of your injection using one of the three available strengths of Myrelez® (60, 90 or 120mg).
If you are well controlled on your treatment, your doctor can recommend a change in the frequency of your Myrelez® 120 mg injections to one injection every 42 or 56 days. Any change in dose will depend on your symptoms and how you respond to the medicine.
Your doctor will also decide how long you 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. Your doctor may adapt the dose of your injection using one of the three available strengths of Myrelez® (60, 90 or 120 mg).
If you are well-controlled on your treatment, your doctor can recommend a change in the frequency of your Myrelez® 120 mg injections to one injection every 42 or 56 days.
Your doctor will also decide how long you 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.

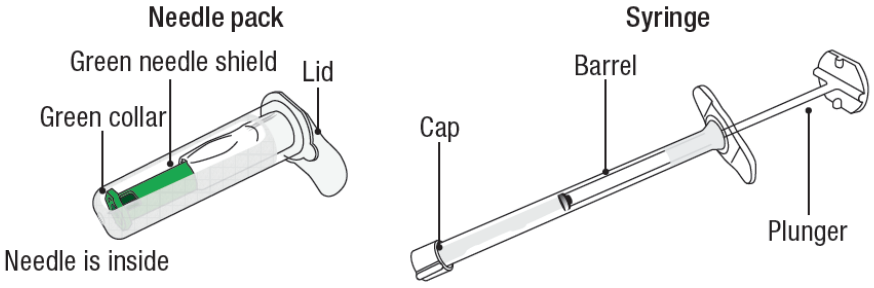
The recommended dose is 120 mg every 28 days. Your doctor will decide how long you should be treated with Myrelez® for tumour control.

Method of administration
Myrelez® 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 you are injecting yourself 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 your doctor.

INSTRUCTION FOR USE

A. What's in the box

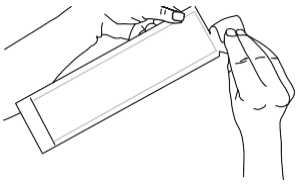
The following instructions explain how to inject Myrelez®
Please read all instructions carefully before starting the injection.

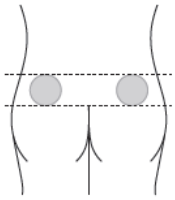


The content of the prefilled syringe is a semi-solid phase having a gel-like appearance, with viscous characteristics and a colour varying from white to pale yellow. The supersaturated solution can also contain micro bubbles that can clear up during injection. These differences are normal and do not interfere with the quality of the product.

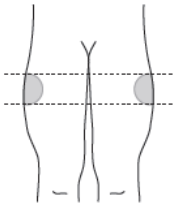
B. Before your start

B1. Remove Myrelez® from the refrigerator 30 minutes prior to injecting. 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.





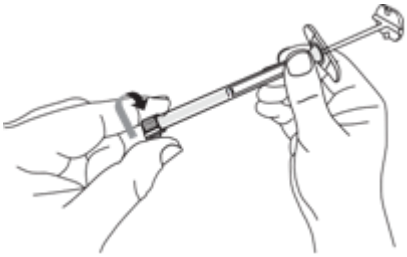
If you are injecting someone else: Inject into the upper outer area of the **buttock**.



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 Myrelez®.

C. Get the syringe ready

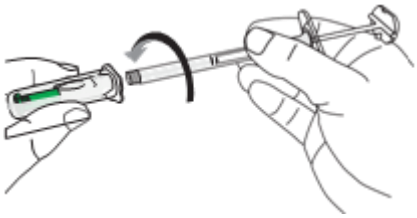


C1: Remove the cap from the syringe

- 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

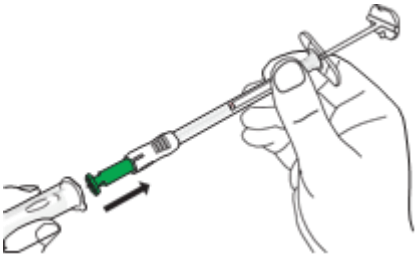
- Hold the needle pack and pull the lid off.
- Caution: Do not touch the open end of the needle pack. This needs to stay clean.



C3: Put the end of the syringe into open end of the needle pack

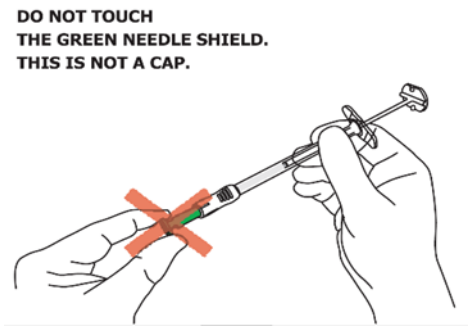
- Hold the needle pack with one hand.
- With the other, hold the syringe barrel steady (**not the plunger**) and twist until the syringe and needle are fully locked together.
- **They are fully locked when you cannot turn it any further.**

Important: Tight the syringe firmly to avoid drug leakage.



C4: Remove the needle from the pack

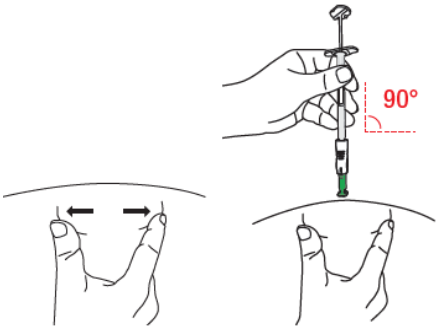
- Hold the syringe barrel (**not the plunger**).
- Pull the needle straight out from the needle pack **without twisting or turning** to make sure that the syringe is well connected to the safety needle.



Caution: The needle is partially exposed from thisstep onwards.

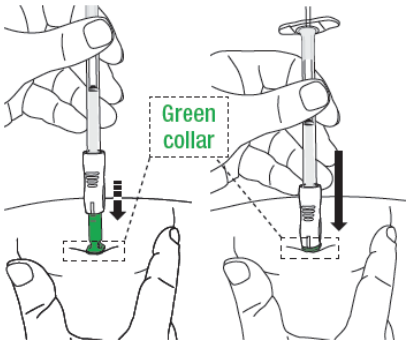
• NEVER TOUCH OR TRY TO OPEN THE GREEN NEEDLE SHIELD
• GREEN NEEDLE SHIELD is NOT a removable cap or cover for the needle.
• GREEN NEEDLE SHIELD will automatically activate during the needle insertion.
• GREEN NEEDLE SHIELD will automatically cover and lock around the needle once the injection is complete.
• GREEN NEEDLE SHIELD is a self-operating safety lock mechanism.

D. Perform injection



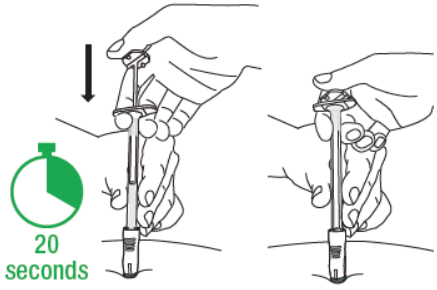
D1: Position the syringe

- 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

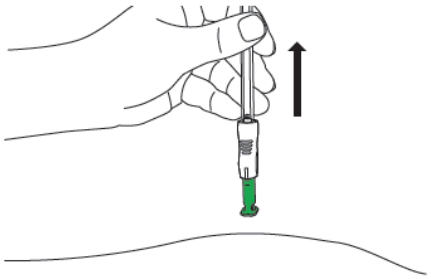
- Without folding or pressing on the skin at the injection site, push the needle firmly against the skin.
- The Green needle shield will retract, and the safety mechanism will activate
- **Keep going until only the collar of the Green needle shield is visible.**
- **Do not** push the plunger in this 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.

If you use more Myrelez® than you should
If you have injected more Myrelez® than you should, please tell your doctor.
If you have injected or if you are given too much Myrelez® you may experience additional or more severe side effects (see section 4 “Possible Side Effects”).

If you forget to use Myrelez®
As soon as you realise that you have missed an injection, contact your healthcare professional, who will give you advice about the timing of your next injection. Do not self-inject extra injections to make up for a forgotten injection, without discussing with your healthcare professional.

If you stop using Myrelez®
An interruption of more than one dose or early termination of the Myrelez® treatment can affect the success of the treatment. Please talk to your doctor before you stop the treatment.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you notice any of the following side effects:

- Feeling more thirsty or tired than usual, and having a dry mouth. These may be signs that you have high blood sugar levels or are developing diabetes.
- Feeling hungry, shaky, sweating more than usual or feeling confused. These may be signs of low blood sugar levels.

The frequency of these side effects is common, it may affect up to 1 in 10 people.

Tell your doctor immediately if you notice that:
- Your face becomes flushed or swollen or you develop spots or a rash
- Your chest feels tight, you become short of breath or wheezy
- You feel faint, possibly as a result of a drop in blood pressure.

These might be the result of an allergic reaction.
The frequency of these side effects is not known; it cannot be estimated from the available data.

Other side effects
Tell your doctor or pharmacist if you notice any of the following side effects.

The most commonly expected side effects are gastrointestinal disorders, gallbladder problems and injection site reactions. The side effects that could occur with Myrelez® are listed according to their frequencies below.

Very common: may affect more than 1 in 10 people:
- Diarrhoea, loose stools, abdominal pain
- Gallstones and other gallbladder problems. You may have symptoms such as severe and sudden abdominal pain, high fever, jaundice (yellowing of the skin and whites of the eyes), chills, loss of appetite, itchy skin.

Common: may affect up to 1 in 10 people:
- Weight loss
- Lack of energy
- Slow heart beat
- Feeling very tired
- Decrease in appetite
- Feeling generally weak
- Excess fat in the stools
- Feeling dizzy, having a headache
- Loss of hair or less development of body hair
- Pain that affects muscles, ligaments, tendons and bones
- Reactions where the injection is given such as pain or hard skin
- Abnormal liver and pancreas test results and changes in blood sugar levels
- Nausea, vomiting, constipation, passing wind, stomach bloating or discomfort, indigestion
- Biliary dilatation (enlargement of the bile ducts between your liver and gallbladder and the intestine). You may have symptoms such as stomach pain, nausea, jaundice and fever

Uncommon: may affect up to 1 in 100 people:
- Hot flushes
- Difficulty sleeping
- A change in the colour of the stools
- Changes to sodium and alkaline phosphatase levels, shown in blood tests

Not known:frequency cannot be estimated from the available data:
- Sudden, severe pain in your lower stomach. This may be a sign of an inflamed pancreas (pancreatitis).
- Abscess at the site of injection which may feel fluid-filled when pressed (redness, pain, warmth and swelling which may be associated with fever)
- Inflammation of the gallbladder (cholecystitis) - you may have symptoms such as severe and sudden pain in the upper right or centre abdomen, the pain may spread to the shoulder or back, tenderness of the abdomen, nausea, vomiting and high fever
- Pain in the upper right part of your belly (abdomen), fever, chills, yellowing of the skin and eyes (jaundice), nausea, vomiting, clay-coloured stools, dark urine, tiredness – these may be signs of inflammation of the bile duct (cholangitis).

Since Myrelez® may alter your blood sugar levels, your doctor may want to monitor your blood

sugar levels especially at the initiation of the treatment.
Similarly, as gallbladder problems can occur with this type of medicine, your doctor may want to monitor your gallbladder when you start receiving Myrelez®, and from time to time afterwards.
Tell your doctor or pharmacist if you notice any of the side effects above.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Myrelez®

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label after [EXP]. The expiry date refers to the last day of that month.
After opening the protective aluminum pouch, the product should be administered immediately.

Store Myrelez® in a refrigerator (2°C – 8°C) in the original package in order to protect from light.
Each syringe is packed individually.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Myrelez® contains
- The active substance is lanreotide (60 mg, 90 mg or 120 mg)
- The other ingredients are water for injection and glacial acetic acid (for pH adjustment)

What Myrelez® looks like and contents of the pack
Myrelez® is a viscous solution for injection in a 0.5 mL semi-transparent plastic syringe accompanied with a single use needle-safe device. It is a white to pale yellow semi-solid formulation.
Each pre-filled syringe is packed in an aluminium pouch and in a carton box.
Box of 0.5 mL syringe with one co-packaged safety needle (1.2 mm x 20 mm).
Multipack with 3 boxes, each containing one 0.5 mL syringe with one co-packaged safety needle (1.2 mm x 20 mm).
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
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Rodopi 69300,
Greece

Amdipharm Limited is part of the ADVANZ PHARMA Group

This medicinal product is authorised in the Member States of the EEA under the following Names:

Denmark:	Myrelez® 60mg injektionsvæske, opløsning i fyldt injektionssprøjte
	Myrelez® 90mg injektionsvæske, opløsning i fyldt injektionssprøjte
	Myrelez® 120mg, injektionsvæske, opløsning i fyldt injektionssprøjte
Austria:	Mytolac® 60 mg Injektionslösung in einer Fertigspritze
	Mytolac® 90 mg Injektionslösung in einer Fertigspritze
	Mytolac® 120 mg Injektionslösung in einer Fertigspritze
Belgium:	Mytolac 60 mg solution injectable en seringue préremplie
	Mytolac 90 mg solution injectable en seringue préremplie
	Mytolac 120 mg solution injectable en seringue préremplie
Czech Republic:	Mytolente
Estonia:	Myrelez
Finland:	Myrelez® 60mg injektioneste, liuos esitäytetyssä ruiskussa
	Myrelez® 90mg injektioneste, liuos esitäytetyssä ruiskussa
	Myrelez® 120mg injektioneste, liuos esitäytetyssä ruiskussa
France:	Myrelez L.P. 60mg solution injectable à libération prolongéeen seringue préremplie
	Myrelez L.P. 90mg solution injectable à libération prolongéeen seringue préremplie
	Myrelez L.P. 120mg solution injectable à libération prolongée en seringue préremplie
Germany:	Mytolac® 60mg Injektionslösung in einer Fertigspritze
	Mytolac® 90mg Injektionslösung in einer Fertigspritze
	Mytolac® 120mg Injektionslösung in einer Fertigspritze
Greece:	Myrelez® 60mg ενέσιμο διάλυμα σε προγεμισμένη σύριγγα
	Myrelez® 90mg ενέσιμο διάλυμα σε προγεμισμένη σύριγγα
	Myrelez® 120mg ενέσιμο διάλυμα σε προγεμισμένη σύριγγα
Hungary:	Mytolac 60 mg oldatos injekció előretöltött fecskendőben
	Mytolac 90 mg oldatos injekció előretöltött fecskendőben
	Mytolac 120 mg oldatos injekció előretöltött fecskendőben
Ireland:	Myrelez® 60mg solution for injection in prefilled syringe
	Myrelez® 90mg solution for injection in prefilled syringe
	Myrelez® 120mg solution for injection in prefilled syringe
Italy:	Myrelez®
Latvia:	Myrelez® 60mg šķīdums injekcijām pilnšļircē
	Myrelez® 90mg šķīdums injekcijām pilnšļircē
	Myrelez® 120mg šķīdums injekcijām pilnšļircē
Lithuania:	Myrelez® 60mg injekcinis tirpalas užpildytame švirkšte
	Myrelez® 90mg injekcinis tirpalas užpildytame švirkšte
	Myrelez® 120mg injekcinis tirpalas užpildytame švirkšte
Netherland:	Mytolac 60 mg oplossing voor injectie in een voorgevulde spuit
	Mytolac 90 mg oplossing voor injectie in een voorgevulde spuit
	Mytolac 120 mg oplossing voor injectie in een voorgevulde spuit
Norway:	Myrelez® 60mg injeksjonsvæske, oppløsning i ferdigfylt sprøyte
	Myrelez® 90mg injeksjonsvæske, oppløsning i ferdigfylt sprøyte
	Myrelez® 120mg injeksjonsvæske, oppløsning i ferdigfylt sprøyte
Poland:	Myrelez®
Portugal:	Myrelez® 60mg solução injetável em seringa pré-cheia MG
	Myrelez® 90mg solução injetável em seringa pré-cheia MG
	Myrelez® 120mg solução injetável em seringa pré-cheia MG
Romania:	Mytolac® 60mg soluţie injectabilă în seringă preumplută

	Mytolac® 90mg soluţie injectabilă în seringă preumplută
	Mytolac® 120mg soluţie injectabilă în seringă preumplută
Slovakia:	Mytolente® 60 mg injekčný roztok naplnený v injekčnej striekačke
	Mytolente® 90 mg injekčný roztok naplnený v injekčnej striekačke
	Mytolente® 120 mg injekčný roztok naplnený v injekčnej striekačke
Spain:	Myrelez® 60mg Solucion inyectable en jeringa precargada EFG
	Myrelez® 90mg Solucion inyectable en jeringa precargada EFG
	Myrelez® 120mg Solucion inyectable en jeringa precargada EFG

This leaflet was last revised in 07/2023.