Mytolac®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Mytolac?

Mytolac contains the active ingredient lanreotide (as acetate). Mytolac is used for the:

- treatment of acromegaly when the circulating levels of growth hormone and IGF-1 remain abnormal after surgery and/or radiotherapy, or in patients who do not respond to therapy with medicines called dopamine agonists
- treatment of symptoms associated with carcinoid syndrome, such as flushing and diarrhoea
- treatment and control of the growth of some advanced tumours of the intestine and pancreas that cannot be removed by surgery (called gastroenteropancreatic neuroendocrine tumours or GEP-NETs) in adult patients.

For more information, see Section 1. Why am I using Mytolac? in the full CMI.

2. What should I know before I use Mytolac?

Do not use if you have ever had an allergic reaction to lanreotide, somatostatin or medicines from the same family or any of the ingredients listed at the end of the CMI. Do not use Mytolac if you are breastfeeding.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Mytolac? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Mytolac and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Mytolac?

- Information on how to inject Mytolac can be found in the **Instructions for administration of the product** at the end of this leaflet.
- For the treatment of acromegaly or the symptoms of carcinoid syndrome, the recommended starting dose is 60 mg to 120 mg injected every 28 days.
- For the treatment of advanced tumours of the intestine and pancreas that cannot be removed by surgery (GEP-NETs), the recommended dose is 120 mg every 28 days.

More instructions can be found in Section 4. How do I use Mytolac? in the full CMI.

5. What should I know while using Mytolac?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Mytolac. • Tell your doctor if you are diabetic. • Tell your doctor if you have any heart problems.
Things you should not do	• Do not stop using this medicine suddenly.
Driving or using machines	• Mytolac is unlikely to affect your ability to drive or use machines, however possible side effects such as dizziness may occur with this medicine. If you are affected be careful when driving or using machinery.
Looking after your medicine	• Store Mytolac at 2°C - 8°C in a refrigerator. Do not freeze. Protect from light.

For more information, see Section 5. What should I know while using Mytolac? in the full CMI.

6. Are there any side effects?

More common side effects of Mytolac are related to the gastrointestinal tract and possible occurrence of gallstones. Serious side effects may be allergic reaction or gallstone complications.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Mytolac®

Active ingredient: *lanreotide (as acetate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Mytolac. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Mytolac.**

Where to find information in this leaflet:

1. Why am I using Mytolac?

Mytolac contains the active ingredient lanreotide (as acetate). Lanreotide is an antigrowth hormone. Lanreotide is an octapeptide, an analogue of a naturally occurring hormone, somatostatin. Lanreotide lowers the levels of hormones in the body such as GH (growth hormone) and IGF-1 (insulin-like growth factor-1).

Mytolac is used for the:
- treatment of acromegaly when the circulating levels of growth hormone and IGF-1 remain abnormal after surgery and/or radiotherapy, or in patients who do not respond to therapy with medicines called dopamine agonists
- treatment of symptoms associated with carcinoid syndrome, such as flushing and diarrhoea
- treatment and control of the growth of some advanced tumours of the intestine and pancreas that cannot be removed by surgery (called gastroenteropancreatic neuroendocrine tumours or GEP-NETs) in adult patients.

2. What should I know before I use Mytolac?

Warnings

Do not use Mytolac if you:

- are allergic to lanreotide, somatostatin or medicines from the same family (analogues of somatostatin), or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- are breastfeeding.

Check with your doctor if you:

- are a diabetic
- have ever experienced liver or kidney problems
- have ever experienced gallstones
- have any thyroid problems, as lanreotide may slightly decrease your thyroid function
- have any heart problems, as slow heart rate may occur during lanreotide treatment.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Do not breastfeed if you are taking Mytolac.

Use in children

Mytolac is not recommended for use in children.

3. What if I am taking other medicines?

Tell your doctor if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Mytolac may interfere with the effect of other medicines which include:

- medicines which reduce the heart rate (e.g. beta-blockers)
- ciclosporin, a medicine used to treat certain problems with the immune system
- bromocriptine, a medicine used to treat Parkinson's disease
- medicines broken down by certain liver enzymes such as quinidine or terfenadine.

Dose adjustments of these may be considered by your doctor.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Mytolac.

4. How do I use Mytolac?

How much to use

- For the treatment of acromegaly or the symptoms of carcinoid syndrome, the recommended starting dose is 60 mg to 120 mg injected every 28 days. Depending on your response to the product, your doctor may vary the dose or the injection frequency.

- For the treatment of advanced tumours of the intestine and pancreas that cannot be removed by surgery (GEP-NETs), the recommended dose is 120 mg every 28 days. Your doctor will decide how long you should be treated with lanreotide for tumour control.
- Follow the instructions provided and use Mytolac until your doctor tells you to stop.

How to administer Mytolac

- Mytolac is intended for deep injection under the skin. It is for single use only.
- Please refer to section **Instructions for administration of the product** at the end of this leaflet.

If you forget to use Mytolac

Mytolac should be used regularly every 28 days. If you miss your dose at the usual day, contact your doctor who will then advise when your next injection is to be given.

Do not self-inject extra doses to make up for a forgotten injection without discussing with your doctor.

If you use too much Mytolac

As Mytolac is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. Mytolac comes in a syringe pre-filled with the dose your doctor has prescribed.

However, if you think that you have used too much Mytolac, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Mytolac?

Things you should do

Call your doctor straight away if you:

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

Things you should not do

- Do not stop using this medicine suddenly.

Monitoring

- If you are diabetic, your doctor may check your blood sugar levels and possibly alter your anti-diabetic treatment while you are receiving Mytolac.
- If you have heart problems, your doctor may check your heart rate and possibly alter your treatment while you are taking Mytolac.
- Due to the possibility of gallbladder problems with this type of medicine, your doctor may want to conduct a gallbladder scan when you start receiving Mytolac and again at regular intervals thereafter.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Mytolac affects you.

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

Looking after your medicine

- Store Mytolac at 2°C - 8°C in a refrigerator. Store in its original package to protect from light. Do not freeze.
- The syringe inside its sealed pouch can be temporarily stored outside of the refrigerator up to a maximum of 24 hours (make sure the temperature stays below 40°C). Return the syringe to the refrigerator as soon as possible for continued storage and use.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

Do not use it if the aluminium pouch is damaged or opened.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• bowel problems including diarrhoea or loose stools, abdominal pain • nausea, vomiting, heartburn, abdominal bloating or discomfort, passing wind or constipation	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

• changes in blood sugar levels (low and high), aggravation of diabetes • slowing of the heart rate • tiredness • headache, dizziness • hair loss or no hair growth • moderate and short-lived pain at the injection site, sometimes with redness, swelling, itching tenderness or abscess • changes in some liver or pancreas test results • weight loss • lack of energy • feeling generally weak • decrease in appetite • pain that affects muscles, ligaments, tendons and bones • excess fat in the stools • enlargement of the bile ducts (symptoms may be stomach pain, nausea, jaundice and fever)	

Serious side effects

Serious side effects	What to do
• gallstones or gallstone complications (signs may be sudden, severe abdominal pain that may spread to the shoulder or back, tenderness of the abdomen, feeling nauseous, vomiting, fever, chills, loss of appetite, itchy skin, having dark urine, clay-coloured stools or yellowing of the skin and eyes (jaundice)) • allergic reaction (symptoms may include flushed or swollen face, developing spots or a rash, feeling tight in the chest, being short of breath or wheezy, feeling faint)	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. In New Zealand, you can report side effects to the Centre for Adverse Reactions Monitoring online at https://nzphvc.otago.ac.nz/reporting/.

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

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Mytolac contains

Active ingredient (main ingredient)	lanreotide (as acetate)
Other ingredients (inactive ingredients)	glacial acetic acid water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What Mytolac looks like

Mytolac is a white to pale yellow viscous solution for injection.

Mytolac is supplied in a pre-filled syringe which is placed in a plastic tray and sealed inside an aluminium pouch. A separately packed automatic single use safety needle is also provided.

One syringe and one safety needle are packaged inside a cardboard box.

Mytolac 60 mg: Aust R 371881
Mytolac 90 mg: Aust R 371880
Mytolac 120 mg: Aust R 371879

Who distributes Mytolac

Distributed in Australia by:
Amdipharm Mercury (Australia) Pty Ltd
Level 9, 76 Berry Street
North Sydney NSW 2060
Ph: 1800 627 680

Distributed in New Zealand by:
Mercury Pharma (NZ)
39 Anzac Road
Browns Bay
Auckland 0753
Ph: 0800 565 633

Amdipharm Mercury (Australia) Pty Ltd is an ADVANZ PHARMA company

This leaflet was prepared in April 2023.

Instructions for administration of the product

Your doctor may suggest that the injection can be given by yourself or your carer. Your doctor or nurse will give you or your carer the appropriate training and confirm that you are both motivated and capable of doing this. Your doctor will continue to supervise the long-term management of your condition.

If the injection is being administered by a healthcare professional or your carer, the injection will usually be given as a deep subcutaneous injection in the upper, outer external quadrant of the buttock.

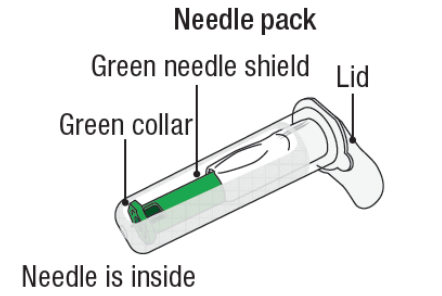
If you are giving the injection to yourself, the deep subcutaneous injection should be given in the upper, outer thigh. The injection site should be alternated between right and left sides.

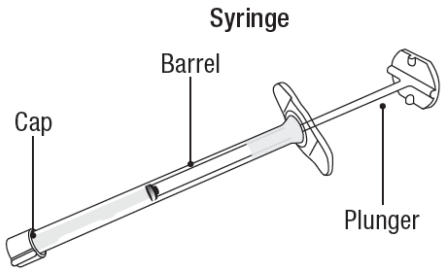
Instructions for use

The following instructions explain how to inject Mytolac.

Please read all instructions carefully before starting the injection.

A. What's in the box





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 you start

B1. Remove Mytolac from the refrigerator 30 minutes prior to injecting. Keep the aluminium pouch sealed until just before the injection.

B2. Before opening the pouch, check that it is intact and that the medicine has not expired. The expiry date is printed on the outer carton and the pouch.

Do not use if:

- you drop or damage the pre-filled syringe

- the pre-filled syringe or pouch appear damaged in any way

- the product has expired.

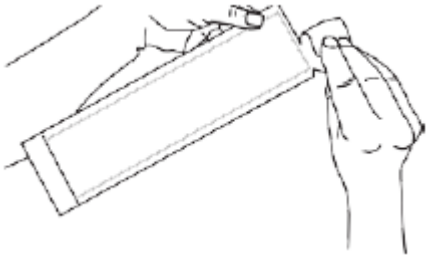
B3. Wash hands with soap and dry hands thoroughly before starting.

B4. Make sure there is a clean surface for preparation.

B5. Choose injection site - the sites are shown below.

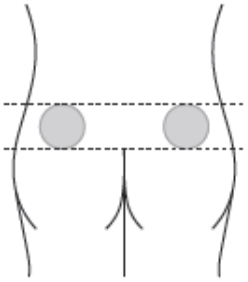
B6. Make sure to clean the injection site.

B7. Tear open the pouch and take out the pre-filled syringe.



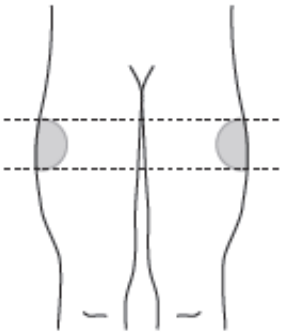
If you are injecting someone else:

Inject into the upper outer area of the buttock.



If you are injecting yourself:

Inject into the upper outer part of your thigh.



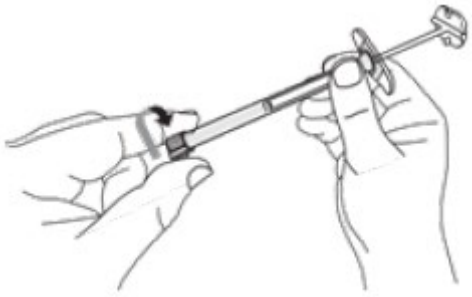
Alternate the injection site between the right and left side each time you have an injection of Mytolac.

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.

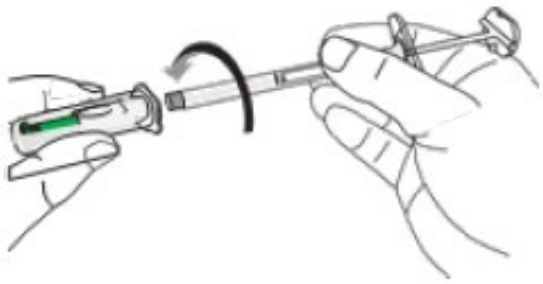
C3: Put the end of the syringe into the open end of the needle pack

•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: Tighten the syringe firmly to avoid medicine leakage.



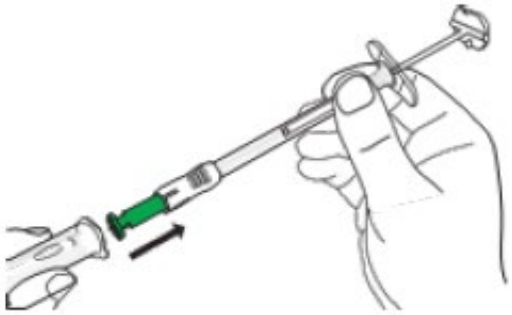
C4: Remove the needle from the pack

• 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.

- NEVER TOUCH OR TRY TO OPEN THE GREEN NEEDLE SHIELD throughout the course of operation of the device.
- Green needle shield is NOT a removable cap or cover for the needle.
- Green needle shield will automatically activate once the injection is complete.
- Green needle shield is a self-operating safety lock mechanism.



D. Perform injection

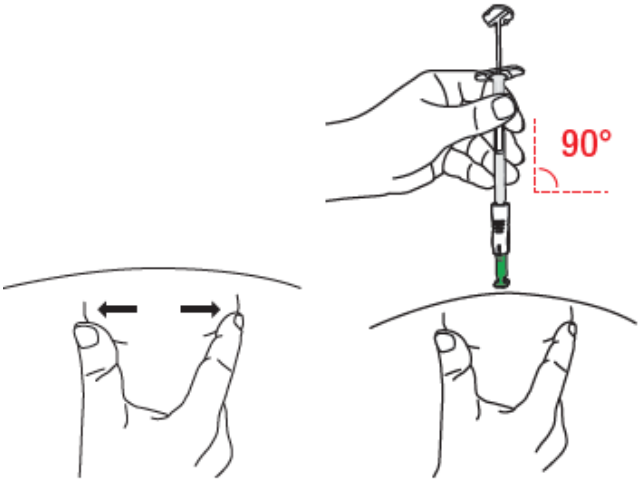
D1: Position the syringe

• 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.

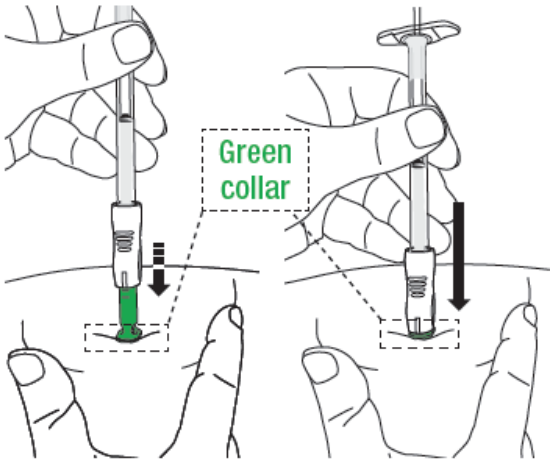
• Hold the lower part of the syringe barrel (not the plunger) with your other hand.

• Position the syringe at a 90-degree angle to the skin.



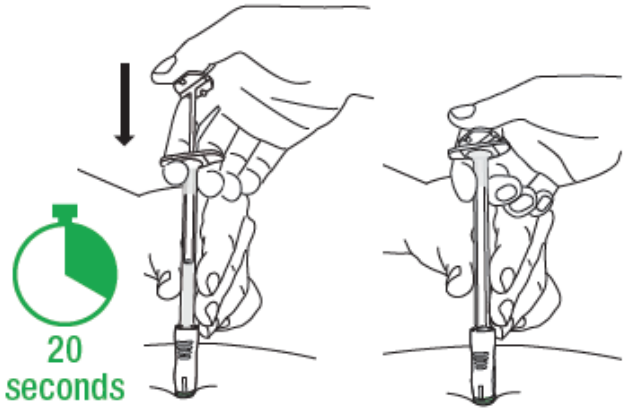
D2: Insert the needle

• Without folding or pressing on the skin at the injection site, push the needle firmly against the skin.
• The **green safety shield** will retract and is now activated.
• 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

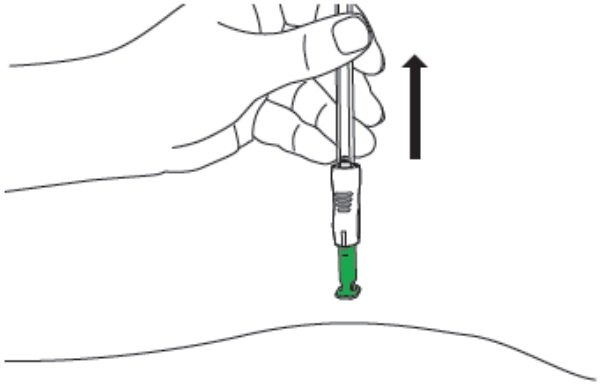
• Move your hand from the skin to the plunger.
• Push the plunger slowly until the top touches the syringe barrel (it is easier to depress the plunger with your dominant hand).
• This should take around 20 seconds.



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 in the syringe disposal container as instructed by your doctor or healthcare professional.
• The needles are not reusable.
• Do not dispose of the syringe or needle in your general household rubbish.