

MY PATIENT MY EXPERTISE MY CHOICE

Nurse & patient discussion guide

KIND DELIVERY



FULL SUPPORT



SAME MOLECULE



SMART PRICE



Prescribing and Adverse Event Reporting information can be found at the end of the document

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Mytolac
LANREOTIDE
SMART CHOICE



INTRODUCTION

An appointment is so much more than the administration of medicine; it is the patient's opportunity to ask questions, seek reassurance or simply to talk to someone who understands.

People with rare diseases such as acromegaly or gastroenteropancreatic neuroendocrine tumours (GEP-NETs), can feel lonely and isolated by their diagnosis,¹ but creating a treatment experience that is as relaxed as possible and providing a reliable source of information can be a big help.





There is growing understanding of how improving patient activation can improve outcomes.² Activation includes assessment of a patient's knowledge, skills and confidence in taking care of their condition, and is related to healthy behaviours, appropriate use of health care systems, preparing for appointments, chronic care self-management and control of chronic illness.² You can increase your patients' activation by:²

- **Supporting them in asking questions**, of you or other members of their care team
- **Tailoring your approach by encouraging small changes** in low activated patients, and supporting greater challenges in those at higher levels

The information covered here is designed to help you feel confident when engaging with your acromegaly and GEP-NETs patients, so they feel empowered to be involved in their treatment decisions and management. If you would like further information on these conditions you can visit the HCP pages of www.advanzforlife.com to find more in-depth details on aetiology, epidemiology and treatment, as well as specific information on MYTOLAC® lanreotide.

ACROMEGALY

From the Greek for extremities (*acro*) and great (*megaly*)

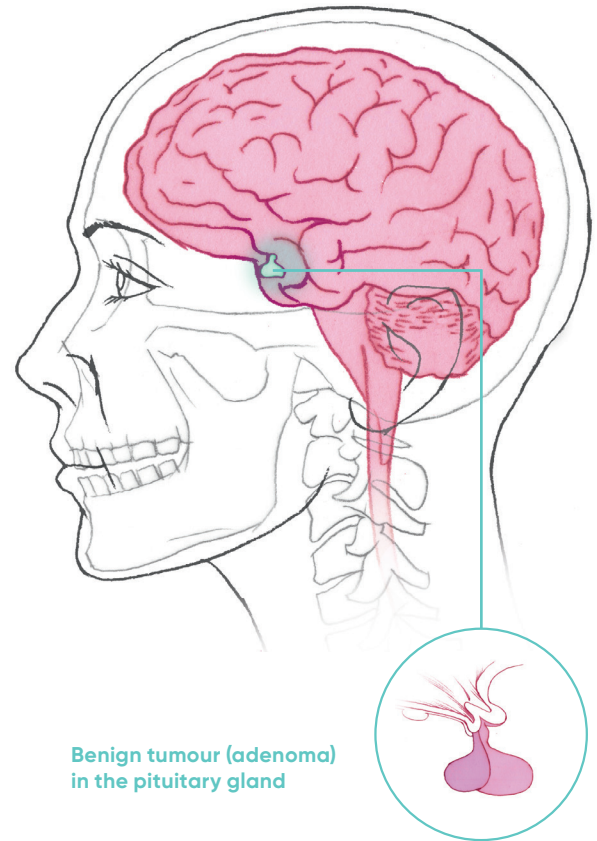


ACROMEGALY

ABOUT ACROMEGALY

Acromegaly is a rare growth hormone disorder usually caused by a benign tumour (adenoma) in the pituitary gland,³ resulting in excessive secretion of growth hormone (GH) and increased levels of insulin-like growth factor-1 (IGF-1).⁴

These, in turn, lead to cell overgrowth, multiple comorbidities and physical disfigurement.⁴ In the vast majority of cases (>95%) acromegaly is due to a sporadic GH-secreting adenoma with no known cause.⁵



ACROMEGALY

THE JOURNEY TO DIAGNOSIS

The effects of increased GH and IGF-1 levels work slowly, with symptoms appearing gradually over time.⁵ Due to this insidious presentation, patients with acromegaly can suffer from diagnostic delays,⁶ sometimes by as much as 5 years from appearance of symptoms to diagnosis.⁵

Patients often feel they have been on a long and challenging path to diagnosis, with years of debilitating symptoms and multiple specialist referrals.⁷

The frustration of this process means that, while they may be relieved to have a name to put to their condition, and the opportunity for treatment,⁷ they can also be left with a feeling of animosity towards the healthcare community.

These feelings are understandable when you consider patients may have undergone unnecessary procedures or experience more pronounced physical changes than if they had been diagnosed earlier.⁷



Acknowledging these emotions, and **keeping communication as open as possible between you, your patient and their consultant**, will help to ensure adherence to treatment and achieve the best outcomes for the patient moving forward.

ACROMEGALY

SYMPTOMS

1 Physical changes

Prominence of the brow
Prognatism
Macroglossia
Hyperhidrosis
Enlargement of the nose and lips
Soft-tissue hypertrophy
Acral overgrowth

2 Metabolic and endocrine complications

Impaired glucose tolerance
Diabetes mellitus
Insulin resistance
Dyslipidaemia
Thyroid goitre

3 Local tumour effects

Headache
Visual impairment
Hyperprolactinaemia
Hypopituitarism

4 Gastrointestinal complications

Colonic polyps
Dolichomegacolon

5 Cardiovascular complications

Hypertension
Biventricular hypertrophy
Cardiomyopathy
Congestive heart failure
Arrhythmias
Valve disease

6 Respiratory complications

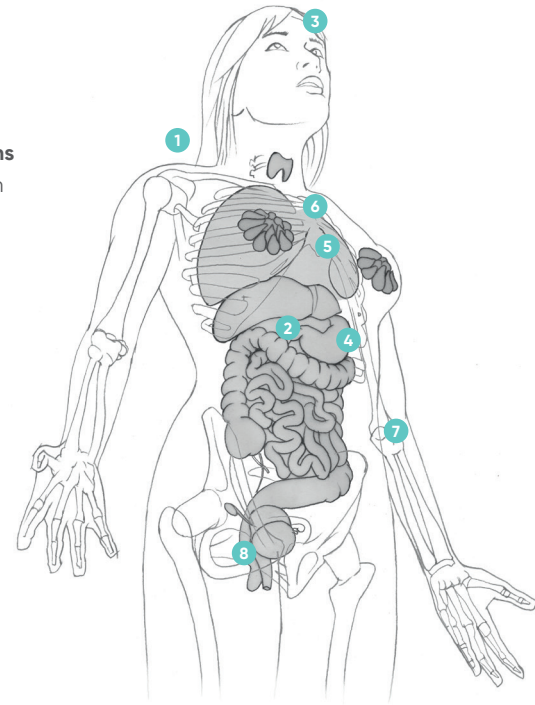
Upper airway obstruction
Ventilatory dysfunction
Sleep apnoea
Excessive snoring

7 Skeletal system complications

Increased articular cartilage thickness
Arthropathy
Carpal tunnel syndrome
Paraesthesia
Vertebral fractures

8 Reproductive disorders

Menstrual disturbance
Erectile dysfunction



The most common symptoms of acromegaly are **changes in facial features and enlargement of the hands and feet**, alongside **nonspecific issues** such as headache, fatigue, hyperhidrosis and joint pain.⁵

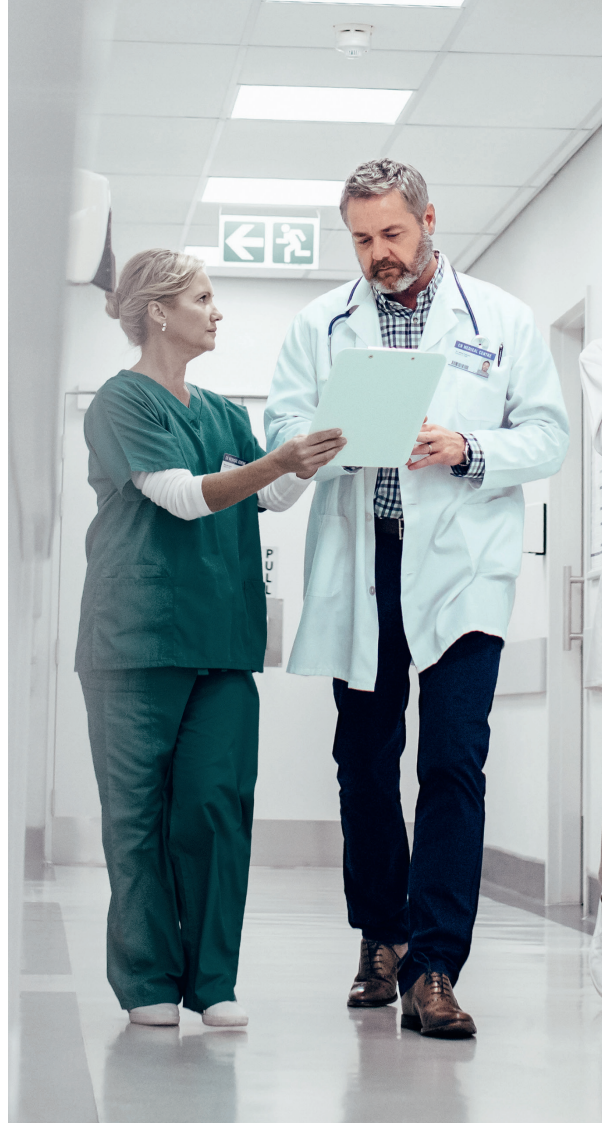
ACROMEGALY

DIAGNOSIS

The Endocrine Society Clinical Practice Guidelines recommend measurement of IGF-1 levels in three instances:⁵

- **Patients presenting with acral and facial changes**
- **Patients with several of the following nonspecific conditions:⁵**
 - a. Sleep apnoea syndrome
 - b. Type 2 diabetes
 - c. Debilitating arthritis
 - d. Carpal tunnel syndrome
 - e. Hyperhidrosis
 - f. Hypertension
- **To rule out acromegaly in a patient with a pituitary mass**

Once the possibility of acromegaly has been recognised the tests to confirm diagnosis are quite simple; IGF-1 levels are measured via a blood test, and if found to be elevated, are followed by an oral glucose tolerance test (OGTT).⁴ If GH levels are not suppressed to $<1 \mu\text{g/L}$ following the induced hyperglycaemia, then acromegaly diagnosis is confirmed.⁴



ACROMEGALY

ASSESSMENT

If biochemical tests have indicated acromegaly an MRI is required to determine the tumour size, location and invasiveness.⁴

Characteristics of the tumour can help predict the level of response to pharmacological treatment, as well as the likelihood of complete surgical removal.⁵

Due to the large and varied number of comorbidities associated with acromegaly, guidelines recommend that when acromegaly is diagnosed, patients are screened and monitored for associated conditions, including: hypertension, diabetes mellitus, cardiovascular disease, osteoarthritis, colon neoplasia and sleep apnoea, and managed accordingly.⁴



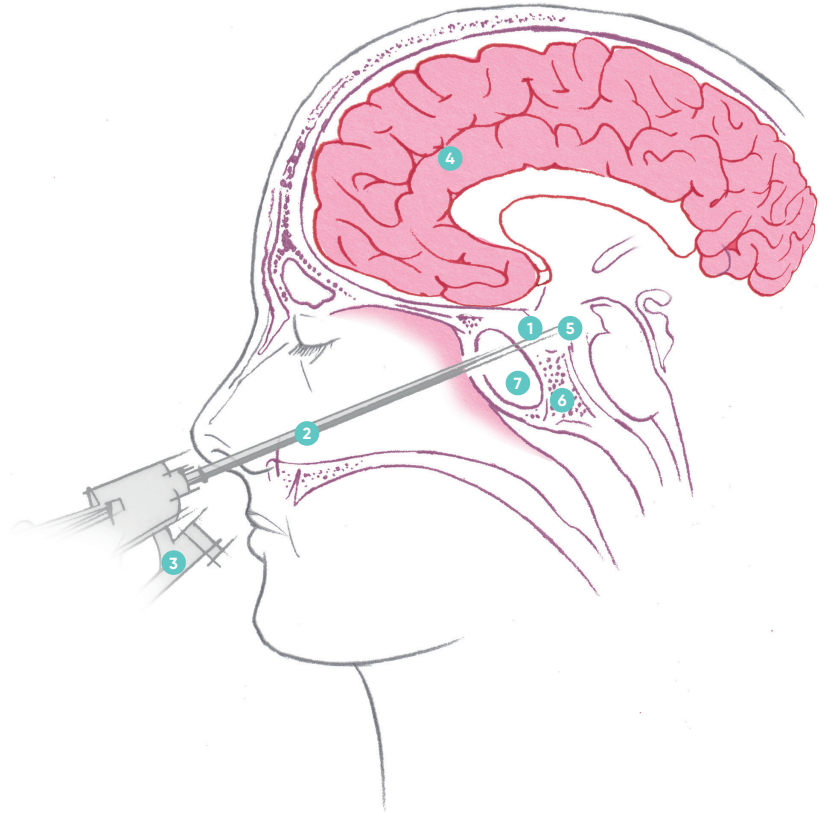
ACROMEGALY

TREATMENT

Transsphenoidal surgery is the first line of treatment for the majority of patients,⁴ aiming to remove all, or as much as possible, of the tumour.⁸

However, surgery does not result in a cure for approximately 50% of patients, and further treatment is required.⁵

- | | |
|-------------|-------------------|
| 1 Adenoma | 5 Pituitary gland |
| 2 Endoscope | 6 Sphenoid bone |
| 3 Curette | 7 Sphenoid sinus |
| 4 Brain | |



PHARMACOLOGICAL TREATMENTS

Somatostatin analogues (SSAs)

Somatostatin analogues are copies of naturally occurring somatostatin – the growth hormone-inhibiting hormone.⁹ The most commonly used SSAs are long-acting release octreotide and lanreotide, which are considered equivalent in terms of biochemical and clinical control and tumour shrinkage.⁵ Biochemical control is achieved in ~55% of patients, but overall efficacy can be hard to assess due to differences in assays and clinical trial design.⁵

Dopamine agonists

Dopamine agonists work to reduce the level of GH produced, however, due to their relatively modest clinical effects, they are recommended as initial post-operative therapy in patients with mild signs and symptoms of excess GH and modest elevations of serum IGF-1.⁴

GH-receptor antagonists

Pegvisomant blocks the production of IGF-1, and although clinical studies have been successful, in practice results are not as positive, possibly due to compliance to the once daily, self-administered injection.⁴

Posology and side effects

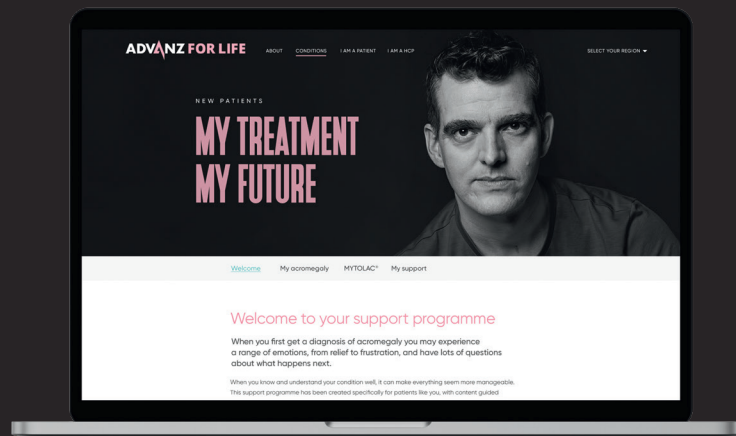
Available doses	
Octreotide ¹⁰	10, 20, 30 mg powder and solvent for suspension
Lanreotide ¹¹	60, 90, 120 mg pre-filled syringe
Pasireotide ¹²	10, 20, 30, 40, 60 mg powder and solvent for suspension
Pegvisomant ¹³	10, 15, 20, 25, 30 mg powder and solvent for solution
Cabergoline ¹⁴	0.5 mg tablets

Administration	Side effects (most common)
Deep intramuscular injection every 4 weeks.	Gastrointestinal, nervous system, hepatobiliary and metabolism and nutritional disorders
Deep subcutaneous injection every 28 days. For controlled patients 120 mg can be given every 6–8 weeks	Gastrointestinal disorders, cholelithiasis and injection site reactions
Deep intramuscular injection every 4 weeks	Hyperglycaemia, gastrointestinal disorders, cholelithiasis and fatigue
Once daily subcutaneous injection	Headache, arthralgia and diarrhoea
Taken orally with food	Gastrointestinal disorders, valvulopathy, fatigue and headache

Your patient has been prescribed MYTOLAC® lanreotide. For more information on this specific treatment, including the benefits of the device and administration video, visit www.advanzforlife.com and select the 'I'm an HCP' pages.

You can register on the website to gain access to more details on all aspects of acromegaly, including aetiology, epidemiology and treatment.

If your patient would like information they can digest in their own time, you can direct them to the same website, www.advanzforlife.com where they can access general information about their condition, but also their specific MYTOLAC® patient support programme using the unique reference number.



GEP-NETS

Gastroenteropancreatic neuroendocrine tumours



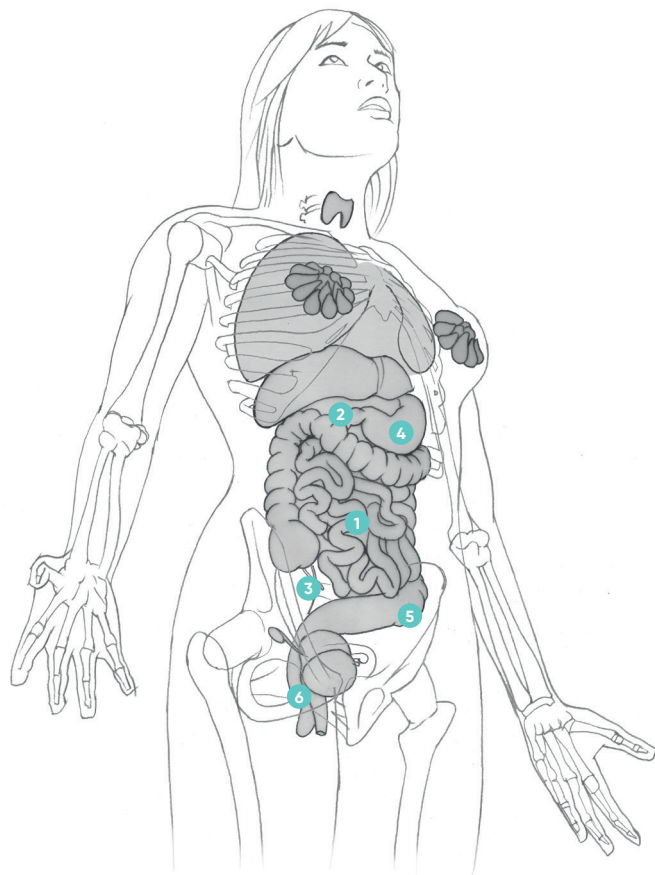
GEP-NETS

ABOUT GEP-NETS

Neuroendocrine tumours (NETs) are rare tumours that can appear anywhere in the neuroendocrine system, the system that controls hormones.¹⁵

When a NET is in the gastroenteropancreatic (GEP) system (digestive tract or pancreas) it is known as a GEP-NET.¹⁶

- | | |
|-------------------|-----------|
| 1 Small intestine | 4 Stomach |
| 2 Pancreas | 5 Colon |
| 3 Appendix | 6 Rectum |



G E P - N E T S

THE JOURNEY TO DIAGNOSIS

Due to their rarity, non-specific symptomology and slow progression, diagnosis of GEP-NETs is often a long and difficult process for patients,¹⁷ with a median time from onset of symptoms to definitive diagnosis of approximately 9.2 years.^{17,18}

A survey of GEP-NET patients found that 80% had visited their GP on average 11 times in relation to their symptoms prior to diagnosis,^{17,18} a process which has a substantially negative impact on patients' personal and work lives.¹⁷

It's easy to imagine that the journey to diagnosis for people with GEP-NETs is distressing, especially when delay has allowed time for tumour progression and metastasis – 58% of patients have metastases at the time of diagnosis¹⁷ – which in turn results in poorer prognosis.¹⁹



As for most cancer diagnoses, patients with GEP-NETs often experience depression.²⁰ An understanding of this, and the journey your patient has been on so far, will help them feel confident in their relationship with you, and keep communication open during treatment.

SYMPTOMS

The symptoms of GEP-NETs are wide ranging, and vary from person to person. Presentation will depend on where the tumour is (e.g. in the pancreas or the small intestine) and whether it is producing hormones (functional) or not (non-functional).²¹

1 General symptoms

- Tiredness
- Loss of appetite
- Unexplained weight loss

2 Symptoms related to where the tumour is:²¹

- Persistent pain in a specific area
- Thickening or a lump in any part of the body
- Nausea or vomiting
- A cough or hoarseness that does not go away
- Changes in bowel or bladder habits
- Jaundice
- Unusual bleeding or discharge

3 Symptoms related to the release of hormones (depending on where the tumour is):²¹

- Diarrhoea
- Facial flushing, usually without sweating
- Hyperglycaemia
- Hypoglycaemia
- Gastric ulcer disease
- Skin rash
- Confusion
- Anxiety

The similarity of these symptoms to more common conditions and malignancies contributes to the difficult diagnosis and treatment delay experienced by many patients.¹⁸

GEP - NETS

DIAGNOSIS

No definitive test for GEP-NETs exists; diagnosis is made on the basis of a combination of blood and urine tests, scans, biopsy and symptomology.^{22,23}

Tumour marker tests

- Chromogranin A, pancreatic polypeptide, serum neuron-specific enolase and subunit of glycoprotein hormones^{24,25}

Blood test

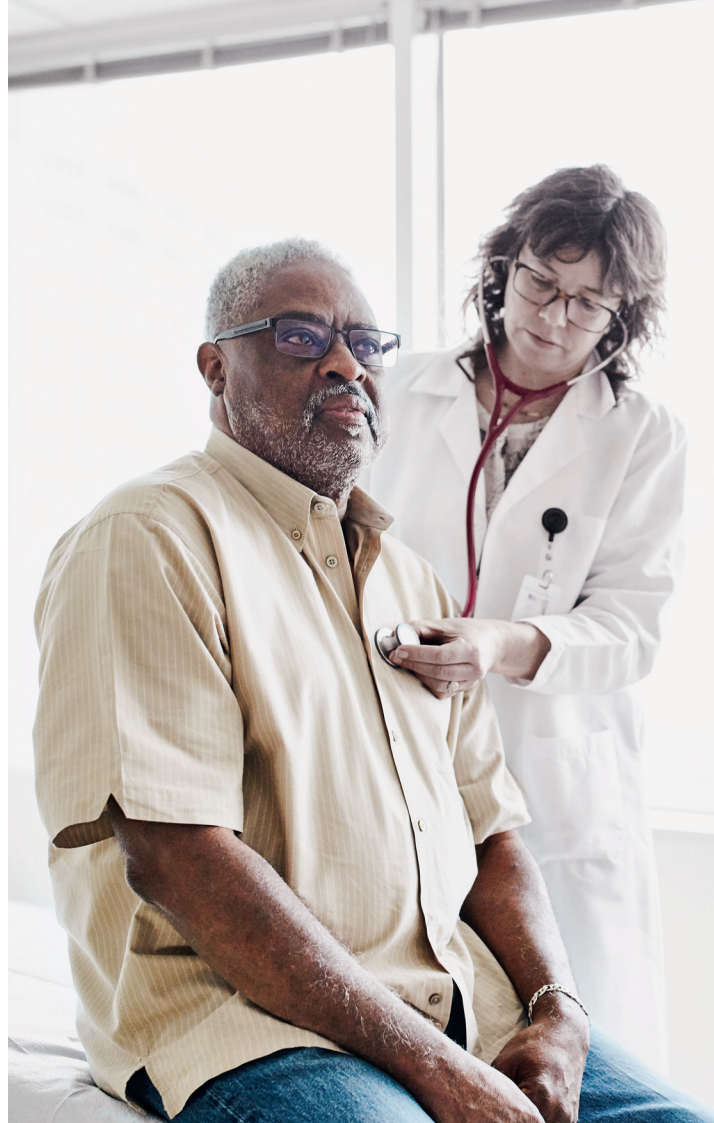
- Full blood count²²

Urine test

- 5-HIAA (5-Hydroxyindoleacetic acid)²⁴

Imaging²⁴

- Conventional radiology such as transabdominal ultrasonography
- Computerised tomography (CT)
- Magnetic resonance imaging (MRI)
- Selective angiography
- Nuclear imaging including somatostatin receptor (SSTR) scintigraphy with single-photon emission CT
- Bone scintigraphy
- Endoscopic ultrasonography



GEP-NETS

ASSESSMENT

GEP-NETs are highly individual and complex conditions to assess, but their most common direct complication is carcinoid syndrome, occurring in around 10% of people with NETs.²⁶

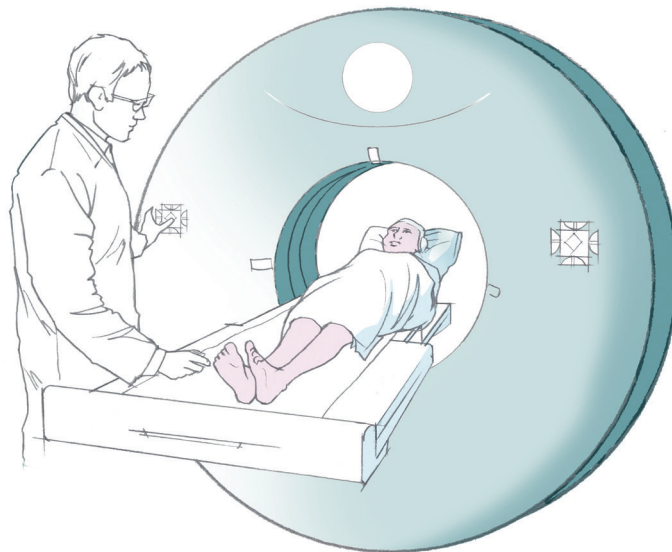
More information on this
can be found on the HCP pages
at www.advanzforlife.com



TREATMENT

Treatment for any particular case of GEP-NETs depends on individual circumstances such as the tumour site of origin, stage and grade of the tumour, and the general health of the patient.²⁷

- **Surgery** is the only potentially curative option, but can also be used for debulking or palliative treatment²⁷
- **Interventional radiology** is used in patients not suitable for surgery, and includes techniques such as radiofrequency ablation, laser ablation and cryotherapy, among others²⁴
- **Reduction in tumour** burden can lead to reduced hormone secretion, and, consequently, an improvement in symptoms²⁴



G E P - N E T S

PHARMACOLOGICAL TREATMENTS

Somatostatin analogues (SSAs)

SSAs are the foundation of current NET drug therapy.²⁴ The two main SSAs are lanreotide and octreotide, which work by inhibiting the release of excess hormones.^{24,28} An inhibition of hormone production is seen in 30-70% with symptom control in the majority of patients.²⁴

Chemotherapy

Chemotherapy is widely used in the treatment of GEP-NETs, however, due to the diversity of the disease, there is no standard regimen.²⁴

Angiogenesis inhibitors

Angiogenesis is essential for tumour development and metastasis,²⁹ and there are a number of treatments which block this process, including the IgG1 monoclonal antibody bevacizumab, and the tyrosine kinase inhibitors (TKIs) sunitinib and sorafenib.^{29,30} Another option is Everolimus, which works as both an angiogenesis inhibitor and targeted growth inhibitor.³¹

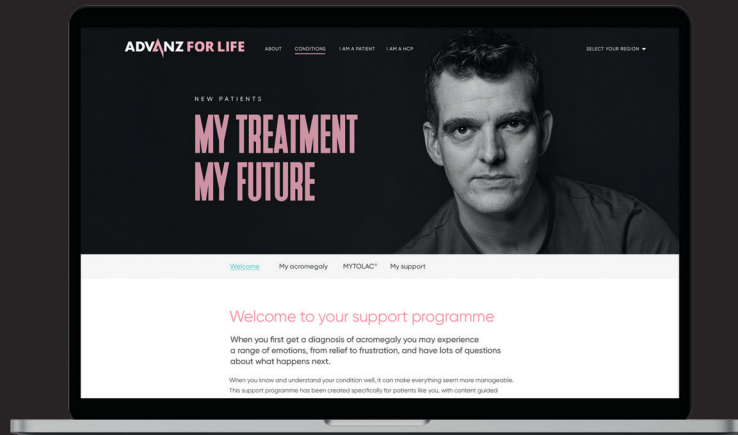




Your patient has been prescribed the SSA MYTOLAC® lanreotide, and for more information on this specific treatment, including the benefits of the device and administration video, visit www.advanzforlife.com and select the 'I'm an HCP' pages and register.

You will also find in-depth coverage of all aspects of GEP-NETs, including its aetiology, epidemiology and treatment.

If your patient would like information they can digest in their own time, you can direct them to the same website, www.advanzforlife.com where they can access general information about their condition, but also their specific MYTOLAC® patient support programme using the unique reference number.



Q&A

This section provides suggested responses to potential questions from your patient in regard to their MYTOLAC® (lanreotide) treatment.

For those who would like further details, or would like to digest information on their own time, you should direct them to the MYTOLAC® (lanreotide) patient support programme via www.advanzforlife.com.au.



Q & A

HOW DOES LANREOTIDE ADVANZ PHARMA WORK?

MYTOLAC® for acromegaly

MYTOLAC® contains the drug lanreotide, a somatostatin analogue. This means it is a copy of the hormone somatostatin which occurs naturally in your body.³² It is also known as growth hormone-inhibiting hormone as one of its main jobs is to stop the production of growth hormone.⁹

Although lanreotide is a copy of natural somatostatin, it is more active and lasts for longer in your body.³²

The tumour causing your acromegaly produces too much growth hormone, which tells your liver to produce lots of another hormone, called insulin-like growth factor-1, or IGF-1 for short.⁴ Lanreotide works to improve your symptoms by reducing the amount of growth hormone and IGF-1 released, and by reducing the size of the tumour.³²

MYTOLAC® for GEP-NETs

MYTOLAC® contains the drug lanreotide, a somatostatin analogue. This means it is a copy of the hormone somatostatin which occurs naturally in your body.³²

However, lanreotide is more active and lasts for longer than natural somatostatin.³² Lanreotide reduces the amount of hormones being produced by your tumour which will help control your symptoms.²⁴ It may also stop your tumour from growing, or reduce its size.²⁴

Why has the name of my treatment changed?

Your previous treatment was also the somatostatin analogue lanreotide, but made by another company. Your new treatment is exactly the same, but you may notice the device is a bit different.

As the medicine inside is the same, you shouldn't experience any changes in how you feel after your treatment, or with any side effects. However, as always, if you do notice anything different please don't hesitate to contact us.

MYTOLAC[®] lanreotide also comes with a patient support programme, with a section for experienced patients like you.

For patients who were receiving octreotide

Your previous treatment was octreotide, which is also a somatostatin analogue, but does not come in a pre-filled syringe. Octreotide and lanreotide are considered equally good treatments,^{4,24} with similar side effects, so you shouldn't experience any changes in how you feel after your treatment.

However, as always, if you do notice anything different please don't hesitate to contact us.

Your new treatment, MYTOLAC[®] lanreotide, comes with a patient support programme, with a section for experienced patients like you.

ADMINISTRATION OF LANREOTIDE ADVANZ PHARMA

Can I treat myself at home?

Once you have been having MYTOLAC® for a while, if you are feeling comfortable with the treatment, I can certainly help support you in learning how to give yourself the injection – known as self-administering. We will also need to talk to your doctor and make sure they are happy that self-administration is the best treatment option for you.

There are a couple of other things you will need to think about, such as keeping the medicine in the fridge and out of the reach of children. You will also be given a sharps disposal box to get rid of the device safely.

If you are thinking about self-administration, there is more information and a video to watch available under the 'My MYTOLAC®' section of your support programme.

Can my partner/carer treat me at home?

Once you have been having MYTOLAC® for a while, if you are feeling comfortable with the treatment, and you and your carer or partner are confident, then I can help support your carer or partner in learning how to give you the injection at home.

We will also need to talk to your doctor and make sure they are happy that self-administration is the best treatment option for you.

There are a couple of things you will need to think about, such as keeping the medicine in the fridge and out of the reach of children. You will also be given a sharps disposal box to get rid of the device safely.

If you and your carer or partner would like to learn more about giving your MYTOLAC® treatment at home, you can find more information and instruction videos in the 'My MYTOLAC®' section of your support programme.

I really don't like injections; is there another way I can have this treatment?

Thanks for letting me know, I will make your appointments as relaxed as possible. Unfortunately, there is currently no other way to give you lanreotide, but there are things we can both do to help you feel more comfortable about it. One of the main points to remember is that this treatment is essential for helping you feel better, when you think about your appointment, think about how it is there to benefit you.

We can also discuss what works best for you – do you want to lie down or stand up? Would you like to see the device and have me explain what will happen, or not? The MYTOLAC® device is designed to make it as easy as possible for me to administer, so while you can relax by chatting to me or looking at something on your phone, it will be over as quickly as possible. There are also some other ideas of how to cope with your injections in the 'My MYTOLAC®' section of your support programme.

Q & A

POTENTIAL SIDE EFFECTS OF MYTOLAC®

Will I get side effects from this treatment?

As with all medications, you may experience some side effects from lanreotide. The most common are stomach issues such as diarrhoea or pain, gallstones or other gallbladder problems and reactions where the injection has been given.³²

However, everyone reacts differently to medication, so if you notice anything unusual or are worried, you can always contact us. You can also find more details on potential side effects in the 'My MYTOLAC®' section of your support programme.

References:

1. Nobel, J. The loneliness of orphan diseases. Available at: <https://www.psychologytoday.com/ca/blog/being-unlonely/201903/the-loneliness-orphan-diseases>. Last accessed September 2020.
2. Greene J, Hibbard JH. Why Does Patient Activation Matter? An Examination of the Relationships Between Patient Activation and Health-Related Outcomes. *J Gen Intern Med*. 2011;27(5):520–526.
3. Endocrine web. Acromegaly causes. Available at: <https://www.endocrineweb.com/conditions/acromegaly/acromegaly-causes>. Last accessed November 2020.
4. Katznelson L, et al. Acromegaly: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab*. 2014;99:3933–3951.
5. Colao A, et al. Acromegaly. *Nat Rev Dis Primers*. 2019;5:1-17.
6. Lavrentaki A, et al. Epidemiology of acromegaly: review of population studies. *Pituitary*. 2017;20(1):4–9.
7. Gurel M, et al. Patient perspectives on the impact of acromegaly: results from individual and group interviews. *Patient Prefer Adherence*. 2014;8:53–62.
8. Endocrine Web. Acromegaly surgery. Available at: <https://www.endocrineweb.com/conditions/acromegaly/acromegaly-surgery>. Last accessed September 2020.
9. Endocrine Web. Acromegaly medications. Available at <https://www.endocrineweb.com/conditions/acromegaly/medications-acromegaly>. Last accessed December 2020.
10. Sandostatin LAR (octreotide) Summary of Product Characteristics. February 2020.
11. MYTOLAC (lanreotide) Summary of Product Characteristics.
12. Signifor (pasireotide) Summary of Product Characteristics. August 2020.
13. SOMAVERT (pegvisomant) Summary of Product Characteristics. October 2020.
14. Cabaser (cabergoline) Summary of Product Characteristics. June 2018.
15. MSD Manual. Endocrine function. Available at: <https://www.msdmanuals.com/home/hormonal-and-metabolic-disorders/biology-of-the-endocrine-system/endocrine-function>. Last accessed September 2020.
16. Everyday Health. What are gastroenteropancreatic neuroendocrine tumors (GEP-NETs). Available at: www.everydayhealth.com/gastroenteropancreatic-neuroendocrine-tumors-gep-nets/. Last accessed January 2021.
17. Singh S et al. 2017. Patient-Reported Burden of a Neuroendocrine Tumor (NET) Diagnosis: Results From the First Global Survey of Patients With NETs *J Glob Oncol*. 2017;3(1):43–53.

18. Basuroy R et al. Delays and routes to diagnosis of neuroendocrine tumours. *BMC Cancer*. 2018;18:1122.
19. Cancer.Net. GI tract NETs; stages and grades. Available at <https://www.cancer.net/cancer-types/neuroendocrine-tumor-gastrointestinal-tract/stages-and-grades>. Last accessed October 2020.
20. Lewis et al. Health-related quality of life, anxiety, depression and impulsivity in patients with advanced gastroenteropancreatic neuroendocrine tumours. *World J Gastroenterol*. 2018 Feb 14; 24(6): 671–679.
21. Cancer.Net. NET symptoms and signs. Available at: <https://www.cancer.net/cancer-types/neuroendocrine-tumors/symptoms-and-signs>. Last accessed September 2020.
22. Macmillan. Diagnosis of neuroendocrine tumours. Available at https://www.macmillan.org.uk/cancer-information-and-support/neuroendocrine-tumours-nets#diagnosis_of_neuroendocrine_tumours_nets. Last accessed December 2020.
23. Living with NETs. Tumor marker tests. Available at <https://www.livingwithnets.com/en-us/tumor-marker-tests/>. Last accessed December 2020.
24. Diez M, et al. Gastroenteropancreatic neuroendocrine tumours: diagnosis and treatment. *Ann Gastroenterol* 2013;26(1):29–36.
25. Sansone A et al. Specific and Non-Specific Biomarkers in Neuroendocrine Gastroenteropancreatic Tumors. *Cancers* 2019;11(8): 1113.
26. NORD. Carcinoid syndrome. Available at <https://rarediseases.org/rare-diseases/carcinoid-syndrome/>. Last accessed December 2020.
27. NHS. Neuroendocrine tumours. Available at: <https://www.nhs.uk/conditions/neuroendocrine-tumours/>. Last accessed January 2021.
28. CRUK. What are somatostatin analogues. Available at <https://www.cancerresearchuk.org/about-cancer/neuroendocrine-tumours-nets/treatment/somatostatin-analogues/what-are>. Last accessed December 2020.
29. Capozzi et al. Antiangiogenic Therapy in Pancreatic Neuroendocrine Tumors. *Anticancer Research*. 2016;36:5025–5030.
30. Carrasco P, et al. Sprouting strategies and dead ends in anti-angiogenic targeting of NETs. *J Molecular Endocrinology*. 2017;59(1):R77–R91.
31. Macmillan. What is Everolimus (Afinitor)? Available at: <https://www.macmillan.org.uk/cancer-information-and-support/treatments-and-drugs/everolimus>. Last accessed January 2021.
32. MYTOLAC® Summary of Product Characteristics.

PRESCRIPTION INFORMATION

Mytolac® lanreotide (as acetate) Solution for injection

Presentation: Solution for injection in a pre-filled syringe. It is a white to pale-yellow semi-solid formulation and is formulated as a prolonged-release solution of lanreotide acetate for deep subcutaneous injection. Prolonged release of the peptide is achieved by the physical nature of the supersaturated solution

Indication: Treatment of acromegaly when the circulating levels of growth hormone and IGF-1 remain abnormal after surgery and/or radiotherapy or in patients who are dopamine agonist treatment refractory, the treatment of symptoms of carcinoid syndrome associated with carcinoid tumours, the treatment of gastroenteropancreatic neuroendocrine tumours (GEP-NETs) in adult patients with unresectable locally advanced or metastatic disease.

Dosage and administration: *Method of administration:* Mytolac should be injected via the deep subcutaneous route in the superior external quadrant of the buttock by a healthcare professional. The deep subcutaneous injection should be given at varying places in the buttock or in the upper outer thigh. *Acromegaly:* In patients receiving a somatostatin analogue for the first time, the recommended starting dose is 60 mg of lanreotide administered every 28 days. *Symptoms of carcinoid syndrome:* The recommended starting dose is 60 to 120 mg administered every 28 days. The dose should be adjusted according to the degree of symptomatic relief obtained. *Treatment of gastroenteropancreatic neuroendocrine tumours in adult patients with unresectable locally advanced or metastatic disease:* The recommended dose of Mytolac is one injection of 120 mg administered every 28 days. The treatment with Mytolac should be continued for as long as needed for tumour control.

Contraindications: Mytolac should not be prescribed during lactation, nor in patients presenting with hypersensitivity to the peptide or related peptides or any of the excipients

Special warnings and precautions for use: Pharmacological studies in animals and humans show that lanreotide, like somatostatin and its analogues inhibit secretion of insulin and glucagon. Hence, patients treated with lanreotide may experience hypoglycaemia or hyperglycaemia. Slight decreases in thyroid function have been seen during treatment with lanreotide in acromegalic patients, though clinical hypothyroidism is rare. Thyroid function tests are recommended where clinically indicated. Lanreotide may reduce gall bladder motility and therefore, gall bladder echography is advised at the start of treatment and every six months thereafter. There have been post-marketing reports of gallstones resulting in complications, including cholecystitis, cholangitis, and pancreatitis, requiring cholecystectomy in patients taking lanreotide. If complications of cholelithiasis are suspected, discontinue lanreotide and treat appropriately. In patients with hepatic/renal dysfunction, kidney and liver function should be regularly monitored. Lanreotide may lead to a decrease of heart rate without necessarily reaching the threshold of bradycardia in patients without an underlying cardiac problem. In patients suffering from cardiac disorders prior to lanreotide initiation, sinus bradycardia may occur and therefore heart rate should be monitored. Care should be taken when initiating treatment with lanreotide in patients with bradycardia.

Interactions: Effect of other medicinal products on lanreotide. Concomitant administration of bradycardia-inducing drugs (i.e. beta blockers) may have an additive effect on the slight reduction of heart rate associated with lanreotide. Dose adjustments of such concomitant medications may be necessary. Effect of lanreotide on other medicinal products The gastrointestinal effects of lanreotide may result in the reduction of the intestinal absorption of co-administered drugs. As with other somatostatin analogues, lanreotide may reduce the intestinal absorption of ciclosporin A. Concomitant administration of ciclosporin with lanreotide may decrease the

relative bioavailability of ciclosporin and therefore may necessitate the adjustment of ciclosporin dose to maintain therapeutic levels. Interactions with highly plasma bound drugs are unlikely in view of the moderate binding of lanreotide to serum proteins (78% mean serum binding). Limited published data indicate that concomitant administration of somatostatin analogues and bromocriptine may increase the availability of bromocriptine. The limited published data available indicate that somatostatin analogues may decrease the metabolic clearance of compounds known to be metabolised by cytochrome P450 enzymes, which may be due to suppression of growth hormone. Since it cannot be excluded that lanreotide may have this effect, other drugs mainly metabolised by CYP3A4 and which have a low therapeutic index (e.g. quinidine, terfenadine) should therefore be used with caution.

Pregnancy and lactation: Not recommended during pregnancy, unless the potential expected benefit clearly justifies the potential risk to the foetus.

Undesirable effects: *Very Common:* Diarrhoea, loose stools, abdominal pain, Cholelithiasis. *Common:* Hypoglycaemia, Dizziness, headache, Sinus bradycardia, Nausea, vomiting, dyspepsia, flatulence, abdominal distension, abdominal discomfort, constipation, Biliary dilatation, Alopecia, hypotrichosis, Fatigue, injection site reactions (pain, mass, induration, nodule, pruritus), ALAT increased, ASAT abnormal, ALAT abnormal, blood bilirubin increased, blood glucose increased, glycosylated haemoglobin increased, weight decreased. *Uncommon:* Diabetes mellitus aggravated, hyperglycaemia, Insomnia, Hot flush, Faeces discoloured, Asthenia, ASAT increased, blood alkaline phosphatase increased, blood bilirubin abnormal, blood sodium decreased.

Overdose: Animal data do not predict any effects other than those on insulin and glucagon secretion and the gastrointestinal system. If overdosage occurs, symptomatic management is indicated.

One spontaneous report of an overdose of the prolonged release microparticle formulation of lanreotide was reported in a 52 year old patient, with a medical history of diabetes mellitus and hypertension, who had received as a result of drug misuse 30 mg lanreotide per day for 2 months. No acute symptoms or pharmacological signs of overdose were reported. The patient died of an acute myocardial infarction, one week after the last dose.

Legal category: POM (Prescription only medicine)

Marketing authorisation number:

MYTOLAC lanreotide (as acetate) 120 mg solution for injection pre-filled syringe – AUST R 371879

MYTOLAC lanreotide (as acetate) 90 mg solution for injection pre-filled syringe – AUST R 371880

MYTOLAC lanreotide (as acetate) 60 mg solution for injection pre-filled syringe – AUST R 371881

Marketing authorisation holder:

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**PBS Information: This product is listed on the PBS as a
Section 100 item**

Refer to PBS Schedule for full authority information.

