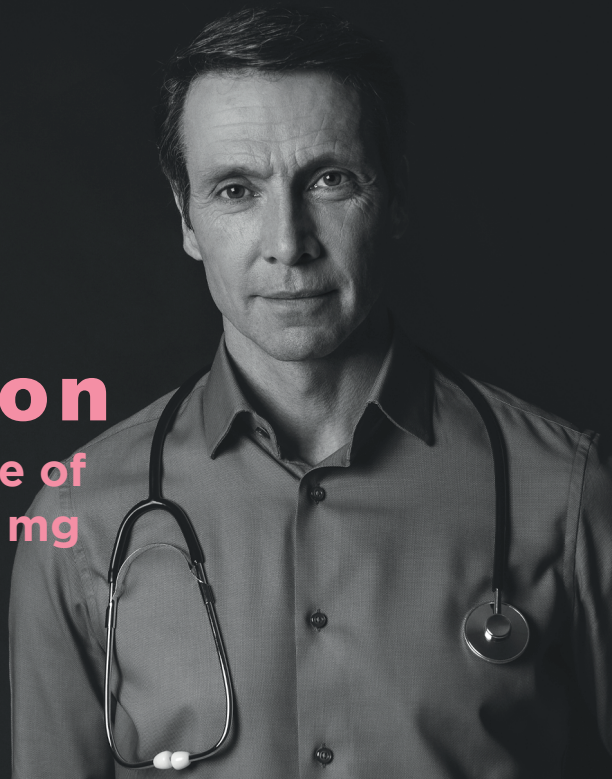




SOLUTION FOR INJECTION IN A PRE-FILLED SYRINGE

HCP Information

Available in pack size of
120 mg, 90 mg & 60 mg



Scan the QR code for useful information



Mytolac HCP
training video



ADVANZFORLIFE
website



Mytolac patient
program website

Please call ADVANZ PHARMA at +612 9431 6333 or
email: medinfo.au@advanzpharma.com for Mytolac
product information or for any other queries.

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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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Ph: 1800 627 680

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Refer to PBS Schedule for full authority information.**