הודעה על החמרה (מידע בטיחות) בעלון לרופא

<u>תאריך: 27.12.2016</u>

<u>Somatuline PR 30 MG 117 93 22911 00 :</u> שם תכשיר באנגלית ומספר הרישום

שם בעל הרישום : מדיסון פארמה בע״מ

טופס זה מיועד לפרוט ההחמרות בלבד !

	ההחמרות המבוקשות		
טקסט חדש	טקסט נוכחי		פרק בעלון
 4.4 Special warnings and precautions for use Lanreotide may reduce gallbladder motility and lead to gallstone formation. Therefore patients may need to be monitored periodically. It is advised, during prolonged treatment, to perform before treatment and every 6 months, an echography of the gallbladder (see section 4.8). 	 4.4 Special warnings and precautions for use Lanreotide may reduce gallbladder motility and lead to gallstone formation. Therefore patients may need to be monitored periodically. It is advised, during prolonged treatment, to perform before treatment and every 6 months, an echography of the gallbladder 	4.4	Special warnings and precautions for use
• Pharmacological studies in animals and humans show that lanreotide, like somatostatin and other somatostatin analogues, inhibits secretion of insulin and glucagon. Hence, patients treated with lanreotide may experience hypoglycaemia or hyperglycaemia. Blood glucose levels should be monitored when lanreotide treatment is initiated, or when the dose is altered. Any antidiabetic treatment should be adjusted accordingly. In insulin-treated diabetic patients, the insulin doses will initially be reduced by 25%, then adapted to the blood glucose level, which must be carefully controlled in these patients as soon as treatment begins.	 Pharmacological studies in animals and humans show that lanreotide, like somatostatin and other somatostatin analogues, inhibits secretion of insulin and glucagon. Hence, patients treated with lanreotide may experience hypoglycaemia or hyperglycaemia. Blood glucose levels should be monitored when lanreotide treatment is initiated, or when the dose is altered. Any antidiabetic treatment should be adjusted accordingly. In insulin-treated diabetic patients, the insulin doses will initially be reduced by 25%, then adapted to the blood glucose level, which must be carefully controlled in these patients as soon as treatment begins. 		
 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. In acromegalic patients and patients presenting with primitive thyrotropic adenomas, use of lanreotide is not exempt from the monitoring of the 	 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. In acromegalic patients and patients presenting with primitive thyrotropic 		

 volume of the pituitary tumour. In patients without underlying cardiac problems, lanreotide may lead to a decrease of heart rate without necessarily reaching the threshold of bradycardia. In patients suffering from pre-existing cardiac disorders, sinus bradycardia may occur. Care should be taken when initiating treatment with lanreotide in patients with bradycardia (see section 4.5). In carcinoid tumours, lanreotide must not be prescribed before having eliminated the presence of an obstructive intestinal tumour. The appearance of a significant and lasting increase of steatorrhoea justifies the complementary prescription of pancreatic extracts. 				eshold of ers, sinus treatment re having	 adenomas, use of lanreotide is not exempt from the monitoring of the volume of the pituitary tumour. In patients without underlying cardiac problems, lanreotide may lead to a decrease of heart rate without necessarily reaching the threshold of bradycardia. In patients suffering from pre-existing cardiac disorders, sinus bradycardia may occur. Care should be taken when initiating treatment with lanreotide in patients with bradycardia (see section 4.5). The appearance of a significant and lasting increase of steatorrhoea justifies the complementary prescription of pancreatic extracts. 	
						4.8 Undesirable effects
System organ class	Very common (≥1/10)	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Post- marketing safety experience (frequency known)	 Investigations: Common: ALAT increased, ASAT abnormal, ALAT abnormal, blood bilirubin increased, blood glucose increased, glycosylated haemoglobin increased, weight decreased 	4.0 UNDESIFADIE ETTECTS
Metabolism and nutrition disorders		Hypoglycaemia, decreased appetite**, hyperglycaemia, diabetes mellitus	<mark>diabetes</mark> mellitus hyperglycaemi <mark>a,</mark>		Uncommon: ASAT increased, blood alkaline phosphatase increased, blood bilirubin abnormal, blood sodium decreased • Cardiac disorders Common: Sinus bradycardia	
Psychiatric			Insomnia <mark>*</mark>		Nervous system disorders	
disorders Nervous system		Dizziness,			Common: Dizziness, headache	
disorders Cardiac		headache, lethargy** Sinus bradycardia*			Gastrointestinal disorders	
disorders		olindo bradybardia			Very common: Diarrhoea, loose stools, abdominal pain Common: Nausea, vomiting, constipation, flatulence, abdominal distension, abdominal discomfort, dyspepsia	
Vascular disorders			Hot flushes <mark>*</mark>		Uncommon: Faeces discoloured	
Gastrointestinal disorders	Diarrhoea, loose stools <mark>*</mark> , abdominal pain	Nausea, vomiting, constipation, flatulence, abdominal distension, abdominal discomfort, dyspepsia, steatorrhoea**	Faeces discoloured <mark>*</mark>	Pancreatitis	 Skin and subcutaneous tissue disorders Common: Alopecia, hypotrichosis Metabolism and nutrition disorders Common: Hypoglycaemia Uncommon: Diabetes mellitus, hyperglycaemia Vascular disorders: 	
Hepatobiliary	Cholelithiasis	Biliary dilatation*			Uncommon: Hot flush	
disorders Musculoskeletal and connective tissue disorders		Musculoskeletal pain**, myalgia**			General disorders and administration site conditions: Common: Fatigue, injection site reactions (pain, mass, induration, nodule, pruritus) Uncommon: Asthenia	
Skin and subcutaneous tissue disorders		Alopecia, hypotrichosis <mark>*</mark>			Hepatobiliary disorders Very common: Cholelithiasis	
					Common: Biliary dilatation	

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Common: Hypoglycaemia		
Uncommon: Diabetes mellitus, hyperglycaemia		
Vascular disorders:		
Uncommon: Hot flush		
General disorders and administration site conditions:		
Common: Fatigue, injection site reactions (pain, mass, induration, nodule, pruritus)		
Uncommon: Asthenia		
Hepatobiliary disorders		
Very common: Cholelithiasis		
Common: Biliary dilatation		
Psychiatric disorders:		
Uncommon: Insomnia		
Post-marketing safety experience:		
Post-marketing safety experience has not identified any other relevant		
information other than occasional reports of pancreatitis.		
Reporting of suspected adverse reactions		
Reporting suspected adverse reaction after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.		
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType= AdversEffectMedic@moh.gov.il		
Pharmacotherapeutic group: Antigrowth hormones, ATC code: H01C B03.	Pharmacotherapeutic group: Antigrowth hormones, ATC code: H01C B03.	5.1 Pharmacodynamic
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 SSTR1, 3, and 4. Activity at human SSTR 2 and 5 is the primary mechanism believed responsible for GH inhibition.	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 SSTR1, 3, and 4. Activity at human SSTR 2 and 5 is the primary mechanism believed responsible for GH inhibition.	properties
In addition, Its marked selectivity for the secretion of growth hormone compared to that of insulin, makes this a product suited to the treatment of	Its marked selectivity for the secretion of growth hormone compared to that of insulin, makes this a product suited to the treatment of acromegaly.	

acromegaly.	By inhibiting the synthesis of thyroid stimulating hormone (TSH), lanreotide	
By inhibiting the synthesis of thyroid stimulating hormone (TSH), lanreotide normalised also the thyroid function on patient with thyrotropin-secreting adenomas.	normalised also the thyroid function on patient with thyrotropin-secreting adenomas.	
Furthermore, the inhibitory action of lanreotide on intestinal exocrine secretion, digestive hormones and cellular proliferation mechanisms is particularly interesting for its application in the treatment of the symptoms of endocrine digestive tumours, especially carcinoids. 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 secretion or gastrin secretion. Lanreotide markedly inhibits meal-induced increases in superior mesenteric artery blood flow and portal venous blood flow. Lanreotide significantly reduces prostaglandin E1-stimulated jejunal hydroelectrolytic secretion (water, sodium, potassium and chloride). Lanreotide reduces prolactin levels in acromegalic patients treated long term. Lanreotide is clearly more active than natural somatostatin and shows a much longer duration of action. A randomised, placebo controlled study has investigated the effects of lanreotide PR 30 mg administration every 10 days, on top of concomitant treatment regimen including intravenous corticoids, proton-pump inhibitors, antispasmodics, antiemetics and analgesics in 80 patients with upper intestinal obstruction of malignant origin due to confirmed peritoneal carcinomatosis in palliative care, having at least 2 vomiting episodes per day or a nasogastric tube and for whom, according to recent surgical advice, surgery was inappropriate. Patients having a bowel obstruction which could be explained by a non-malignant cause were excluded from the study.	Furthermore, the inhibitory action of lanreotide on intestinal exocrine secretion, digestive hormones and cellular proliferation mechanisms is particularly interesting for its application in the treatment of the symptoms of endocrine digestive tumours, especially carcinoids. 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. Lanreotide markedly inhibits meal-induced increases in superior mesenteric artery blood flow and portal venous blood flow. Lanreotide significantly reduces prostaglandin E1-stimulated jejunal hydroelectrolytic secretion (water, sodium, potassium and chloride). Lanreotide reduces prolactin levels in acromegalic patients treated long term. Lanreotide is clearly more active than natural somatostatin and shows a much longer duration of action.	

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