

18th CONGRESS of the European NeuroEndocrine Association

17-20 October 2018



Programme Organizing Committee

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Rosario Pivonello (Italy)

Registration Sponsorship and Exhibition Management

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Welcome Message

Dear Colleagues and Friends,

On behalf of the European Neuroendocrine Association we are pleased to invite you to WROCŁAW for the 18th ENEA Congress from 17 to 20 October 2018. Following Vienna, Sofia and Milan it is a perfect time to visit Poland during the season of golden Polish autumn. Wroclaw is located in the heart of Europe with short distance to the capital cities of surrounding countries. The city of Wroclaw has a long multicultural history, influenced by many societies and individuals from the neighbourhood. Currently it is presented as the meeting place and was awarded the European Capital of Culture 2016. We are deeply convinced that you will have an opportunity to discover the true beauty and unusual friendly atmosphere of our city.

We await all scientists and clinicians interested and practicing in neuroendocrinology. The Program Organizing Committee has prepared a balanced program covering basic reports, translational studies and clinical practice. Five plenary lectures, thirteen symposia, nine meet-the-professor, oral communications and poster sessions are planned. You will find a choice of interesting topics and you will have an opportunity to present your recent achievements and reports in neuroendocrinology.

Welcome to Wrocław.

With best greetings,



Prof. Alberto Pereira ENEA President



Prof. Marek Bolanowski Chair LOC



Prof. Jacques Drouin Chair POC

General Information

TRANSPORT FROM THE AIRPORT

By bus

Bus No. 106 goes to/from the Central Bus and Railway Station every day every 20 minutes. The entire journey takes approximately 35 minutes (depending on the traffic).

The detailed timetable is available at www.wroclaw.pl.

The stop in the City Center is "Renoma". Single ticket: 3,4 PLN

WRO AIRPORT EXPRESS

A shuttle bus operates on the route Airport - City Centre (Plac Dominikański) – Dworzec Wrocław (Central Bus and Railway Station). A ticket will cost PLN 10 (to be paid directly to the driver by cash or by card). The journey will take about 30 minutes. Bus operates every 50 minutes.

BY TAXI

Recommended taxi corporation:
Partner Taxi +48 71 19627,
Wicar Taxi +48 71 342 07 77
Approximate charges*
Airport – City Center: 50-70 PLN,
Airport – Central Railway Station: 60-80 PLN
* Day rate. Prices may slightly vary
depending on traffic difficulties (jams,
detours, etc.) Night rate – according to
taximeter.

You will find a variety of taxi corporations at the airport. Our advice would be to ask the driver about the price before you enter the cab. This will help you avoid unpleasant surprises.

PUBLIC TRANSPORTATION

Wrocław offers various means of public transportation. The city is well-connected by buses, trams and trains. If you want to check public transportation connections please visit: www.wroclaw.jakdojade.pl

The Venue can be reached by the lines: 6, 7 (stops: Uniwersytet or Uniwersytecka)

Since the Venue is located in the very City Center you can also use other lines and have a short walk: 3, 4, 10, 23, 33 (stop Świdnicka) or 3, 10, 20, 23, 24, 33 (stop Rynek).

TOURIST INFORMATION

The Meeting Point is open daily from 09:00 till 19:00.

Rynek 14, 50-101 Wrocław phone: +48 71 344 31 11 e-mail: info@itwroclaw.pl

CLIMATE

Wrocław is the warmest city in Poland. The mean temperature in October is around 7.4 degrees Celsius, some rainy days may be expected. Nights can be very chilly.

CURRENCY

The currency of Poland: Polish Złoty (zł, PLN) Currency subunit: Grosz 1/100 (100 groszy = 1 PLN)

Approximate exchange rates:

Approximate exchange ra

1 EUR = 4,28 PLN 1 USD = 3,68 PLN

1 CHF = 3.74 PLN

1 GBP = 4,81 PLN

Credit cards

In general, VISA, EC/MC and American Express credit cards are accepted in most restaurants, cafés, shops and petrol stations.

Stores and shopping

The opening hours of Wrocław stores are generally 09:00-20:00 on weekdays and 09:00-15:00 on Saturday. The big shopping centres are open from 09:00-21:00 from Monday to Saturday and all of them are closed on Sunday.

INTERNET ACCESS

Free WiFi access will be available at the congress venue

COFFEE BREAKS / LUNCHES

Coffee, tea, soft drinks and cookies are served during all breaks.

Lunches will be served at the Venue's Foyers.

Badges

Participants are requested to wear their badge while the Congress takes place.

Smoking

Smoking is allowed only in designated areas.

Parking space around the venue

Please note that the Venue is located in the Old Town so the parking space is limited. Parking spaces around the Venue need to be paid.

Catering

Permanent coffee breaks and lunch boxes will be served to the participants in designated spaces.

The 18th Congress of the European NeuroEndocrine Association has been accredited by the European Accreditation Council for Continuing Medical Education (EACCME®) for a maximum of **22 European CME credits** (ECMEC®s).



FACULTY of LAW ADMINISTRATION and ECONOMICS University of Wrocław

Uniwersytecka 7-10 (building D) 50-145 Wrocław, Poland

The venue is located in Wrocław City Centre, so you can easily reach it by public transportation from the Central Railway Station or from the International Wrocław Airport.

CONGRESS REGISTRATION DESK Opening hours

Wednesday	17 Oct.	11.00 - 17.30
Thursday	18 Oct.	07.30 - 19.00
Friday	19 Oct.	07.30 - 19.00
Saturday	20 Oct.	07.30 - 13.00

COMMERCIAL EXHIBITION Opening hours

Wednesday	17 Oct.	13.00 - 17.00
Thursday	18 Oct.	09.00 - 18.00
Friday	19 Oct.	09.00 - 18.00
Saturday	20 Oct.	09.00 - 13.00

MEDIA CHECK Opening hours

Wednesday	17 Oct.	11.00 - 17.30
Thursday	18 Oct.	07.30 - 18.00
Friday	19 Oct.	07.30 - 18.00
Saturday	20 Oct.	07.30 - 13.00

WEDNESDAY October 17, 2018

12:45 – 13:00	OPENING CEREMONY	Room
13:00 – 13:35	PLENARY 1	Room
	ROLF GAILLARD PRIZE Lecture Chair: Thierry Brue (FR) Prolactin, hyperprolactinemia and prolactinomas: a renewed interest Philippe Chanson (FR)	
13:35 – 14:10	PLENARY 2	Room
	Chair: Alberto Pereira (NL) Neuroendocrine tumors Wouter W. de Herder (NL)	
14:15 – 15:45	SYMPOSIUM 1	Room
	Development of hypothalamo-pituitary system Chair: Cynthia Andoniadou (UK)	
14:15 – 14:40	Patterning of neuroendocrine hypothalamus Marina Placzek (UK)	
14:40 – 15:05	Role of Shh in hypothalamo-pituitary development Juan-Pedro Martinez-Barbera (UK)	
15:05 – 15:30	3D atlas of the human hypothalamus Paolo Giacobini (FR)	
15:30 – 15:45	Abstract 29 - The effect of long-term exposure to mode high ambient temperature on rat pituitary corticotropes: immunohistomorphometric and hormonal study Milica Potrebic (RS)	
15:45 – 16:00	COFFEE Break	

16:00 – 17:30	SYMPOSIUM 2	Room 1
*.	Prognosis of pituitary adenomas Chair: Davide Carvalho (PT)	
16:00 – 16:25	Outcome of NFPAs Niki Karavitaki (UK)	
16:25 – 16:50	Prognostic classification of pituitary tu Jacqueline Trouillas (FR)	mors
16:50 – 17:15	Cushing's long term outcome Nienke Biermasz (NL)	
17:15 – 17:30	Abstract 183 - Efficacy of Pasireotide LA somatostatin analogue resistant acrom experience from a large and single cen Sabrina Chiloiro (IT)	legaly patients:
17:30	Welcome Reception	Venue

THURSDAY October 18, 2018

08:00 - 08:45

MEET THE PROFESSOR



Room 5

Aggressive pituitary tumours

Filip Gołkowski (PL)



Room 2

Metabolic consequences of acromegaly and its treatment

Jens Otto Jorgensen (DK)

Room 6

Tools for genomic data analysis Mads Lerdrup (DK)

08:45 – 09:15	PLENARY 3 Room
	Chair: Jacques Drouin (CA)
	Diversity of hypothalamic neurons Tibor Harkany (SE)
09:15 – 10:45	SYMPOSIUM 3 Room
	The hypothalamo-pituitary-gonadal axis Chair: Lucio Vilar (BR)
09:15 – 09:40	MicroRNAs in the regulation of hypothalamic GnRH production Vincent Prevot (FR)
09:40 – 10:05	Pituitary gonadotrope cells Ulrich Boehm (DE)
10:05 – 10:30	Isolated hypogonadotropic hypogonadism/Kallmann Syndrome Jacques Young (FR)
10:30 – 10:45	Abstract 213 - Direct inhibitory effect of ketoconazole on cell viability, proliferation and apoptosis in ACTH-secreting tumours Roberta Patalano (IT)
10:45 - 11:00	COFFEE Break
11:00 – 12:30	EYRC SYMPOSIUM Room
	The crosstalk between neuroendocrine system and obesity: novel aspects Chair: Maria Tichomirova (LU)
11:00 – 11:25	Mitochondrial bridge between neuroendocrine system and obesity Marc Claret (ES)

11:25 – 11:50	Novel central actions of GLP-1 in obesity Karolina Skibicka (SE)
11:50 – 12:15	Links between circadian clocks, sleep, metabolism and obesity Vikki Revell (UK)
12:15 – 12:30	Abstract 62 - Type 2 diabetes in neuroendocrine tumors: are biguanides and statins part of the solution? Aura D. Herrera-Martínez (ES)
09:30 - 11:30	ORAL COMMUNICATIONS Room 2
	Chair: Ilan Shimon (IL)
09:30 - 09:45	Abstract 195: Effects of replication of the physiological and non-physiological cortisol rhythm on insulin sensitivity in muscle: a molecular in vitro analysis on synchronized muscular cells Mariarosaria Negri (IT)
09:45 – 10:00	Abstract 87: Analysis of factors associated with pasireotide-induced diabetes mellitus in patients with Cushing's disease and role of glycaemic response to an acute pasireotide test in predicting diabetes development under therapy Marialuisa Zilio (IT)
10:00 – 10:15	Abstract 178: Long-term safety and efficacy of pasireotide sc in Cushing's disease: Interim results from a multicentre, non-interventional, observational study of up to 9.9 years Jochen Schopohl (DE)
10:15 - 10:30	Abstract 45: Characterization and natural history of appendiceal neuroendocrine neoplasms: a multicenter retrospective study Gianluca Tamagno (IRL)
10:30 – 10:45	Abstract 214: Parameters of glucose metabolism independently predict post glucose load growth hormone concentrations in patients with acromegaly Greisa Vila (AT)
10:45 – 11:00	Abstract 193: Macimorelin stimulated GH test vs ITT for AGHD diagnosis: posthoc analyses by likelihood of AGHD and a different ITT cutpoint Jose Garcia (US)
11:00 – 11:15	Abstract 151: Symptom burden and impact of treatment in patients with acromegaly treated with injectable somatostatin receptor ligands Maria Fleseriu (US)

Scientific PROGRAMME

THURSDAY October 18, 2018

11:15 – 11:30	Abstract 153: Decompression of the optic chiasm in NFMA patients - systematic review Iris Pelsma (NL)	
11:30 - 13:15	LUNCH	
12:30 – 13:15	ENEA General Assembly Room	2
13:15 – 14:45	NOVARTIS SYMPOSIUM Room	1
	Aspiring to excellence in acromegaly and Cushing's disease Programme chair: Annamaria Colao (IT) Faculty: Maria Fleseriu (US), Martin Reincke (DE)	
14:45 - 15:00	COFFEE Break	
15:00 – 16:30	SYMPOSIUM 5 Room	1
	Central regulation Chair: Günter Stalla (DE)	
15:00 – 15:25	AVP and thirst regulation Charles W Bourque (CA)	
15:25 – 15:50	Oxytocin and stress Alexis Bailey (UK)	
15:50 – 16:15	Inappropriate ADH secretion Mirjam Christ-Crain (CH)	
16:15 – 16:30	Abstract 147: Inhibition of HSF1 suppresses POMC transcription by regulating suppressive mechanisms over its promoter Denis Ciato (DE)	

16:45 - 18:15	SYMPOSIUM 6	Room 1
	Pathogenic mechanisms in pituitary adenomas Chair: Marily Theodoropoulou (DE)	
16:45 – 17:10	Somatic mosaicism and XLAG Adrian Daly (BE)	
17:10 – 17:35	Pituitary tumors in Carney complex Jérome Bertherat (FR)	
17:35 – 18:00	The pathologists's view of McCune-Albright syndrome Albert Thiry (BE)	
18:00 – 18:15	Abstract 179: Switching to long-acting pasireotide providenefit to patients with uncontrolled acromegaly after timore months of treatment with first-generation somators.	hree or
	analogues (SSAs)	
	Gérald Raverot (FR)	
18:15 – 19:00	POSTER SESSION	Foyer/Hall 2 nd floor

20:00 ENEA Network Dinner



FRIDAY October 19, 2018

08:00 - 08:45

MEET THE PROFESSOR



Room 5

Room 2



Pregnancy in rare endocrine diseases

Małgorzata Karbownik-Lewińska (PL)

The endocrine effects of new oncologic treatments Ansgar Heck (NO)

Pitfalls in pituitary imaging Jean François Bonneville (FR)

08:45 – 09:15	PLENARY 4	Room 1
	Chair: Clara Alvarez (ES) Cushing's disease Martin Reincke (DE)	
09:15 – 10:45	SYMPOSIUM 7	Room 1
	Co-morbidities of secreting adenomas Chair: Gregory Kaltsas (GR)	
09:15 – 09:40	Cardiovascular and metabolic complications of Cushing's disease Przemysław Witek (PL)	
09:40 - 10:05	Fractures in pituitary adenoma patients Gherardo Mazziotti (IT)	
10:05 - 10:30	Does acromegaly kill? Olaf M Dekkers (NL)	
10:30 – 10:45	Abstract 231 - Cardiovascular complications in pituitary gigantism (results of an international study) Liliya Rostomyan (BE)	
10:45 - 11:00	COFFEE Break	

11:00 – 12:30	SYMPOSIUM 8	Room 1
	Medullary Thyroid Carcinoma (MTC) Chair: Natalia Pellegata (DE)	
11:00 – 11:25	MEN 2 revisited Frederic Castinetti (FR)	
11:25 – 11:50	Transcriptome and prognosis of MTCs Barbara Jarzab (PL)	
11:50 – 12:15	Targeted therapies in MTCs Manisha Shah (US)	
12:15 – 12:30	Abstract 190: 1,25 hydroxyvitamin D reverses everolimus resistance in hepatocellular carcinoma activating mesench epithelial transition and miR-375 Claudia Pivonello (IT)	nimal-
12:30- 13:15	LUNCH	
13:15 – 14:45	SYMPOSIUM 9	Room 1
	Model systems for neuroendocrine studies Chair: Manuel Gahete Ortiz (ES)	
13:15 – 13:40	Hypothalamic neuro-developmental disorders Gil Levkowitz (IL)	
13:40 – 14:05	Neuroendocrine regulation of energy homeostasis in a mabristle worm Florian Raible (AT)	arine
14:05 – 14:30	Zebrafish, a new model to study neuroendocrine tumors Giovanni Vitale (IT)	
14:30 – 14:45	Abstract 82 - Prolactinomas diagnosed in elderly men: a cohort of 26 males diagnosed after the age of 65 Ilan Shimon (IL)	
14:45 – 15:00	COFFEE Break	

FRIDAY October 19, 2018

15:00 – 16:30	SYMPOSIUM 10 Ro	om :
	Novel mechanisms of neuroendocrine diseases Chair: Maria Chiara Zatelli (IT)	
15:00 – 15:25	Genetics of pituitary hormone deficiencies Mehul Dattani (UK)	
15:25 – 15:50	Growth hormone deficiency Taneli Raivio (FL)	
15:50 – 16:15	High-throughput cancer genomics Roland Rad (DE)	
16:15 – 16:30	Abstract 89 - Peptides derived from the extracellular tail of the sst5TMD4 splice variant increase the malignancy of neuroendocrine and other endocrine-related cancer cells Manuel Gahete Ortiz (ES)	ie
16:00 - 18:00	EYRC ORAL COMMUNICATIONS Ro	om
	Chair: Cristina Olarescu (NO)	
16:00 - 16:15	Abstract 222: USP8 inhibition with a small molecule inhibitor supresses ACTH secretion from human Cushing's disease tumours in vitro Luis Perez-Rivas (DE)	B
16:15 - 16:30	Abstract 141: Use of primary cell cultures from human pituita adenomas reveal a broad therapeutic potential of a newgeneration dopastatin (somatostatin-dopamine) analogue Antonio C Fuentes-Fayos (ES)	ary
16:30 - 16:45	Abstract 79: Somatostatin receptor analogs alter fecal bacteri microbiota in patients with acromegaly: Preliminary results Suleyman Nahit Sendur (TR)	ial
16:45 - 17:00	Abstract 156: Does the use of mean consecutive GH and IGF2 single fasting values impact the discordance rate of target hormones in acromegaly patients? Claudia Campana (IT)	
17:00 - 17:15	Abstract 88: SSTR5 gene expression is regulated by epigenetiand post-transcriptional events in acromegaly	ic
	Sergio Pedraza Arévalo (ES)	

	- 17:30 - 17:45	acromegaly Alexander Lu Abstract 18	assessed by taken to a second	microRNA in present of the microRNA in present of the micro of the mic	n sequen d factors	cing		
17:45 - 18:00		responsiveness to glucocorticoid therapy Sabrina Chiloiro (IT) Abstract 228: Kisspeptin and neurokinin B in regulation in menstrual function in patients with Cushing disease before and after transsphenoidal surgery Svetlana Vorotnikova (RU)						
18:00	- 19:00	POSTER SE	SSION			Foyer/H 2 nd flo		

SATURDAY October 20, 2018

08:00 - 08:45

MEET THE PROFESSOR



Room 5

Macroprolactinemia Agata Bałdys-Waligórska (PL)



Room 2

Hypophysitis Vera Popovic (SR)



Room 6

Emerging pituitary imaging techniques Mark Gurnell (UK)

08:45 - 09:15	PLENARY 5	Room 1		
	Chair: Marek Bolanowski (PL) Growth Hormone John Kopchick (US)			
09:15 – 10:45	SYMPOSIUM 11	Room 1		
	Novel therapies for pituitary adenomas Chair: Patrick Petrossians (BE)			
09:15 – 09:40	Novel treatments for pituitary adenomas Annamaria Colao (IT)			
09:40 - 10:05	Receptor mediated therapies Stefan Schulz (DE)			
10:05 – 10:30	Novel therapies in CD and the Phase 3 SONICS study on Levoketoconazole in CS Maria Fleseriu (US)			
10:30 – 10:45	Abstract 77: Potential role of biguanides in the treatment of two distinct types of intracranial tumors, gliomas and pituitary tumors Antonio C Fuentes-Fayos (ES)			
10:45 - 11:00	COFFEE Break			

11:00 – 12:	30 SYMPOSIUM 12	Room 1
	Registries Chair: Aleksandra Jawiarczyk-Przybyłowska	(PL)
11:00 – 11:2		
	Gerlof D Valk (NL)	
11:25 – 11:5	French Acromegaly registry Luigi Maione (FR)	
11:50 – 12:1	Spanish Molecular Registry of pituitary (REMAH)	adenomas
	Justo Castano (ES)	
12:15 – 12:3	Abstract 120: Primary hypophysitis - a of 60 cases	single centre series
	Felix Amereller (DE)	
12:30	CLOSING	Room 1

About WROCŁAW



As the largest city of Lower Silesia, Wrocław is the region's administrative, economic and cultural capital. It's an academic center with 22 institutions of higher education and over 120,000 students. Standing on twelve islands on the Odra River and its four tributaries, it is often called the Venice of the North. The city's history is a mishmash of influences that speak of the varied cultural influences on a place that was at different times claimed by Prussia, Austria, Germany and, of course, Poland. Thanks to its history the city has become an open-minded, creative center for international business and culture.



TOP 5

ATTRACTIONS AROUND THE VENUE

1.

The Market Square (Rynek) – the Heart of the Old Town

Whether for business, tourism, shopping or a splendid meal, the Market Square is a vibrant centre of city life that offers something for everyone. Set among charming, colourful buildings, the historic centre of the city is a must see in Wrocław. During the day, the Market Square is crowded with tourists and office workers, but at night it becomes the most vibrant entertainment hotspot of the city. Full of colourful restaurants, clubs and cafes, the Market Square barely goes to sleep at all.

2.

The Cathedral Island (Ostrów Tumski)

The oldest part of Wrocław, the Cathedral Island, is surrounded by the waters of the Odra River. A former stronghold, Ostrów Tumski, is a place full of history and inspiring architectural monuments. Its gothic buildings overlook the city, giving a sense of its rich history. The Island is the oldest part of the city (over 1000 years old). Surrounded by the Odra River it has been the foundation of the contemporary city. The architecture and atmosphere of that island are so unique that we're sure you'll fall in love with it!

3.

The Four Denominations District

The Four Denominations District (Dzielnica Czterech Świątyń) is located in the centre of Wrocław, right by the Market Square. The idea of cultural trail involves such actions as restoration of cultural values, which were cultivated in this quarter, and showing the present-day Wrocław's multiculturalism and openness. The Four Denominations District hosts many cultural and educational events. The Synagogue is a place of special significance. Numerous restaurants, cafes, pubs and music clubs located in the Four Denominations District make it one of the most magical meeting places in Wrocław.

4.

The Panorama of Racławice

The Panorama of Racławice is a unique depiction of the Battle of Racławice. 15 meters tall and 114 meters long, the painting by Jan Styka and Wojciech Kossak is housed in a specially constructed rotunda. The ticket to the Panorama also grants admission to the permanent exhibition in the National Museum.

5.

The University of Wrocław (Main Building)

The University of Wrocław is located in the largest baroque complex of the city, formed by the former Jesuit academy and church. It is the oldest alma mater in Wrocław. The main building houses the Museum of the University of Wrocław, which holds the pearl of Lower Silesian baroque, the Aula Leopoldina, and the Oratorium Marianum, a hall in which concerts have been taking place for 200 years as well as the Mathematical Tower houses an old astronomical observatory.







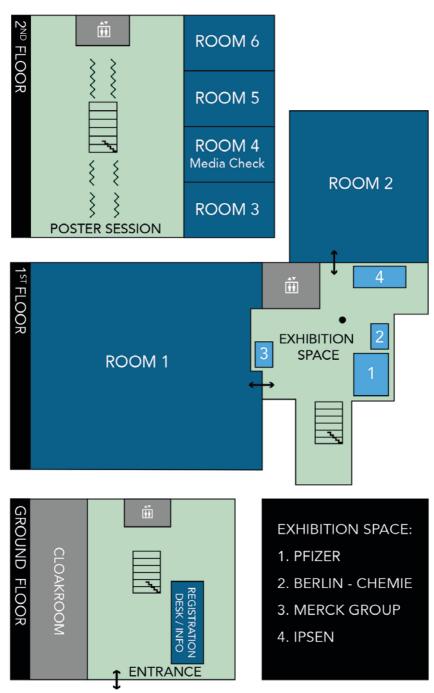
Therapeutic indications:

- The long term treatment of acromegaly when the circulating levels of growth hormone (GH) and (or) insulin-like growth factor (IGF-I) remain abnormal after surgery and (or) radiotherapy, or for whom surgery and (or) radiotherapy is not possible. The aim of therapy in acromegaly is to decrease the GH and IGF-1 concentrations and, if possible, to bring them to normal.
- The relief of symptoms associated with acromegaly.
- The treatment of grade 1 and a subset of grade 2 (Ki67 index up to 10%) gastroenteropancreatic neuroendocrine tumours (GEP-NETs) of midgut, pancreatic or unknown origin where hindgut sites of origin have been excluded, in adult patients with unresectable locally advanced or metastatic disease.
- The treatment of symptoms associated with neuroendocrine tumors.





Somatuline AUTOGEL, 60 mg, 90 mg, 120 mg (Lanreotide), solution for injection in a pre-filled syringe; QUALITATIVE AND QUANTITATIVE COM-POSITION: Lanreotide 60 mg, 90 mg, 120 mg (as lanreotide acetate). Each pre-filled syringe contains a supersaturated solution of lanreotide acetate corresponding to 0.246 mg of lanreotide base/mg of solution, which ensures an actual injection dose of 60 mg, 90 mg and 120 mg of lanreotide, respectively. PHARMACEUTICAL FORM: Solution for injection in a pre-filled syringe. White to pale yellow semi solid formulation. THERAPEUTIC INDICATIONS: Somatuline Autogel is indicated for: - The long term treatment of acromegaly when the circulating levels of growth hormone (GH) and (or) insulin-like growth factor (IGF-I) remain abnormal after surgery and (or) radiotherapy, or for whom surgery and (or) radiotherapy is not possible. The aim of therapy in acromegaly is to decrease the GH and IGF-1 concentrations and, if possible, to bring them to normal. The relief of symptoms associated with acromegaly. The treatment of grade 1 and a subset of grade 2 (Ki67 index up to 10%) gastroenteropancreatic neuroendocrine tumours (GEP-NETs) of midgut, pancreatic or unknown origin where hindgut sites of origin have been excluded, in adult patients with unresectable locally advanced or metastatic disease. - The treatment of symptoms associated with neuroendocrine tumors. POSOLOGY AND METHOD OF ADMINISTRATION: Acromegaly and treatment of symptoms associated with neuroendocrine tumors: The recommended starting dose is 60 to 120 mg administered every 28 days. For example, in patients previously treated with Somatuline PR 30 mg administered every 14 days, the initial dose of Somatuline Autogel should be 60 mg every 28 days, in patients previously treated with Somatuline PR 30 mg administerd every 10 days, the initial dose of Somatuline Autogel should be 90 mg every 28 days and in patients previously treated previously with Somatuline PR 30 mg administered every 7 days, the initial dose of Somatuline Autogel should be 120 mg every 28 days. Thereafter the dose should be modified according to the response of the patient (as judged by a reduction in symptoms and (or) a reduction in GH and/or IGF-I levels). If the desired response is not obtained, the dose may be increased. If complete control is obtained (based on GH levels under 1 ng/ml, normalised IGF-1 levels and/or disappearance of symptoms), the dose may be decreased. Patients well controlled on somatostatin analogue, product Somatuline Autogel can be injected in dose 120 mg every 42 or 56 days. For example, patients well controlled on Somatuline Autogel 60 mg every 28 days can be treated with Somatuline Autogel 120 mg every 56 days and patients well controlled on Somatuline Autogel 90 mg every 28 days can be treated with Somatuline Autogel 120 mg every 42 days. Long term monitoring of symptoms, GH and IGF-I levels should be undertaken as clinically indicated. Treatment of grade 1 and a subset of grade 2 (Ki67 index up to 10%) gastroenteropancreatic neuroendocrine tumours of midgut, pancreatic or unknown origin where hindgut sites of origin have been excluded, in adult patients with unresectable locally advanced or metastatic disease; The recommended dose of Somatuline Autogel 120 mg is one injection administered every 28 days. The treatment with lanreotide Autogel 120 mg should be continued for as long as needed for tumour control. Renal and/or hepatic impairment; In patients with impaired renal or hepatic function, no dosage adjustment is necessary due to the wide therapeutic window of lanreotide. Elderly patients: In elderly patients, no dosage adjustment is necessary due to the wide therapeutic window of lanreotide. Pediatric population: Somatuline Autogel is not recommended for use in children and adolescents due to a lack of data on safety and efficacy. Method of administration: Somatuline Autogel is administered by deep subcutaneous injection in the superior external quadrant of the buttock or in the upper outer thigh. For patients who receive stable dose of Somatuline Autogel, and after appropriate training, the product may be administered either by the patient or by a trained person. In case of self-injection the injection should be given in the upper outer thigh. The decision regarding administration by the patient or a trained person should be taken by a healthcare professional. Regardless of the injection site, the skin should not be folded and the needle should be inserted rapidly and to its full length, perpendicularly to the skin. The injection site should alternate between the right and left side. CONTRAINDICATIONS: Hypersensitivity to somatostatin or related peptides or any of the excipients. SPECIAL WARNINGS AND PRECAUTIONS FOR USE: Lanreotide may reduce gallbladder motility and lead to gallstone formation. Therefore patients may need to be monitored periodically. 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 hypoglycemia or hyperglycemia. Blood glucose levels should be monitored when lanreotide treatment is initiated, or when the dose is altered and any antidiabetic treatment should be adjusted accordingly. 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 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 cardiac disorders prior to lanreotide treatment, sinus bradycardia may occur. Care should be taken when initiating treatment with lanreotide in patients with bradycardia. UNDESIRABLE EFFECTS: Undesirable effects reported by patients suffering from acromegaly and GEP-NETs treated with lanreotide in clinical trials are listed under the corresponding body organ systems according to the following classification: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100). The most commonly expected adverse drug reactions following treatment with lanreotide are gastrointestinal disorders (most commonly reported are diarrhea and abdominal pain, usually mild or moderate and transient), cholelithiasis (often asymptomatic) and injection site reactions (pain, nodules and indurations). The profile of undesirable effects is similar for all indications. System organ class: Infections and infestations; frequency not known: Injection site abscess; Metabolism and nutrition disorders; common: Hypoglycaemia, decreased appetite (based on a pool of studies conducted in patients with GEP-NETs), hyperglycaemia, diabetes mellitus; Psychiatric disorders: uncommon: Insomnia (based on a pool of studies conducted in acromegalic patients); Nervous system disorders: common: Dizziness, headache, lethargy (based on a pool of studies conducted in patients with GEP-NETs); Cardiac disorders: common: Sinus bradycardia (based on a pool of studies conducted in acromegalic patients); <u>Vascular disorders</u>; <u>uncommon</u>: Hot flushes (based on a pool of studies conducted in acromegalic patients); <u>Gastrointestinal disor</u>ders: very common: Diarrhoea, loose stools based on a pool of studies conducted in acromegalic patients), abdominal pain; common: Nausea, vomiting, constipation, flatulence, abdominal distension, abdominal discomfort, dyspepsia, steatorrhoea (based on a pool of studies conducted in acromegalic patients); uncommon: Faeces discoloured (based on a pool of studies conducted in acromegalic patients); unknown: Pancreatitis; Hepatobiliary disorders; very common: Cholelithiasis; common: Biliary dilatation (based on a pool of studies conducted in acromegalic patients); unknown: Cholecystitis; Skin and subcutaneous tissue disorders: common: Alopecia, hypotrichosis (based on a pool of studies conducted in acromegalic patients); General disorders and administration site conditions; common: Asthenia (based on a pool of studies conducted in acromegalic patients), Fatigue, injection site reactions (pain, mass, induration, nodule, pruritus); Investigations: common: AIAT increased (based on a pool of studies conducted in acromegalic patients), ASAT abnormal (based on a pool of studies conducted in acromegalic patients), AIAT abnormal (based on a pool of studies conducted in acromegalic patients), blood bilirubin increased (based on a pool of studies conducted in acromegalic patients), blood glucose increased (based on a pool of studies conducted in acromegalic patients), glycosylated haemoglobin increased (based on a pool of studies conducted in acromegalic patients), weight decreased, pancreatic enzymes decreased (based on a pool of studies conducted in patients with GEP-NETs); Muskuloskeletal and connective tissue disorders; common: (based on a pool of studies conducted in patients with GEP-NETs); Musculoskeletal pain, myalgia; Immune system disorders: unknown: Allergic reactions (including angioedema, anaphylaxis, hypersensitivity); Reporting of suspected adverse reactions: Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reaction via Department of Adverse Events Monitoring the Office of Registration of Medicinal Products, Medical Devices and Biocidal Products: Al. Jerozolimskie 181C; 02-222 Warsaw; Tel.: +48 22 49 21 301; Fax: +48 22 49 21 309; e-mail: ndl@urpl.gov.pl; Adverse events may also be reported to Marketing Authorization Holder. MARKETING AUTHORISATION HOLDER: Ipsen Pharma; 65 Quai Georges Gorse; 92100 Boulogne Billancourt; France; INFORMATION ABOUT THE MADICINAL PRODUCT IS PROVIDED BY: IPSEN Poland Sp. z o.o., Al. Jana Pawla II 29, 00-867 Warsaw, tel.: (22) 653 68 00, fax: (22) 653 68 22. MA NUMBER: 10944 (Somatuline AUTOGEL, 60 mg), 10945 (Somatuline AUTOGEL, 90 mg), 10946 (Somatuline AUTOGEL, 120 mg); CATEGORY: Medicinal product on prescription; Please read Summary of Product Characteristic before use. Last update date: 12.09.2018.



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