

تحت رعاية معالي وزير الصحة الأكرم الأستاذ الدكتور فراس الهواري
Under the Patronage of His Excellency the Minister of Health Prof. Dr. Firas Al-Hawari



المؤتمر العاشر للجمعية الأردنية لاختصاصيي الغدد الصم والسكري وأمراض الاستقلاب

المؤتمر الأردني الفلسطيني الثالث المشترك لأمراض الغدد الصم والسكري

المؤتمر المشترك الأول للجمعية الأردنية لاختصاصيي الغدد الصم والسكري وأمراض
الاستقلاب وجمعية الأطباء الأردنيون لهشاشة العظام

المؤتمر الأول للأكاديمية الدولية لأبحاث الغدد الصم والسكري في الشرق الأوسط وشمال إفريقيا

The 10th International Congress of the Jordanian Society
of Endocrinology, Diabetes & Metabolism (JSED)

The 3rd Joint Jordanian Palestinian Conference
for Endocrinology & Diabetes

The 1st Joint Congress of the Jordanian Society of Endocrinology, Diabetes
& Metabolism (JSED), The Jordanian Physicians Osteoporosis Society (JPOS)

The 1st MENA Regional Endocrinology & Metabolic
Diseases Research Conference



9-11 November
2023

Le Royal Hotel
Amman-Jordan

SCIENTIFIC PROGRAM

CONGRESS TOPICS

- Diabetes
- Thyroid Diseases
- Pituitary Disorders
- Obesity
- Adrenal Disorders
- Osteoporosis & Metabolic Bone Diseases
- Gonadal Dysfunction
- Hot Issues



DAY 1
THURSDAY
9 NOVEMBER, 2023

The 10th International Congress of the Jordanian Society of Endocrinology, Diabetes & Metabolism (JSED)
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16:00-16:30

OPENING CEREMONY

National Anthem

Recitals from the Holy Quran

Chairman of the Scientific Committee Speech

Dr. Munther Momani

President of Jordanian Society of Endocrinology, Diabetes & Metabolism (JSED) Speech

Dr. Abdelkarim Khawaldeh

President of the Jordan Medical Association (JMA) Speech

Dr. Ziad Alzoubi

Congress Patron Speech

Minister of Health, Prof. Dr. Firas Al-Hawari

Master of Ceremony **Dr. Muwafag Hiari**

16:30-17:15

PLENARY
LECTURE

GENETICS IN ENDOCRINOLOGY: UPDATE

Speaker: Prof. Constantine Stratakis (GREECE)

Moderator: Abdelkarim Khawaldeh, MD

17:15-17:45

Coffee Break and Exhibition



SCIENTIFIC PROGRAM



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SESSION 1

Endocrine

Moderators: Fawzi Alhammouri, MD - Abdallah El Eyadeh, MD

- 17:45-18:10 **P₁** Neurological Manifestations of Thyroid Disease During Childhood
Amal Abu Libdeh, MD (JOR)
- 18:10-18:35 **P₂** Diagnosing Endocrine Tumor Syndromes from their Skin Manifestations
Konstantina Kimpouri, MD (GREECE)
- 18:35-18:40 Q&A







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PHARMA SESSION 1

Moderators: Sami Haddad, MD - Nadim Jarrah, MD

- 18:40-19:00  Precision medicine in the new era of T2DM: Prioritizing Cardiorenal risk management
Nadim Jarrah, MD (JOR)  **Boehringer Ingelheim**

- 19:00-19:20  Treatment of Obesity
Sami Haddad, MD (JOR)  **novo nordisk®**

- 19:20-19:30 Q&A



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PHARMA SESSION 2

Moderators: Nidal Al Khatib, MD - Dana Hyassat, MD - Hazem Bilbeisi, MD

19:30-19:50



SGLT-2-Inhibitors: A Revolution in CKD Management
Nidal Al Khatib, MD (JOR)



19:50-20:10



Insulin IDegASP: Translating clinical outcome into real world evidence
Hazem Bilbeisi, MD (JOR)



20:10-20:30



Renal component of the CRM Benefits of Empagliflozin: Insights from EMPA KIDNEY
Dana Hyassat, MD (JOR)



20:30-20:40

Q&A

20:40

Dinner



DAY 2

FRIDAY

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SESSION 2

Osteoporosis / Calcium metabolism

Moderators: Mohamed El-Zaheri, MD - Rashad Nasr, MD - Bassam Taher, MD - Nahla Khawaja, MD

08:30-08:55

P₃

New results on Lebanese Vitamin D status and consequences

Ghada El-Hajj Fuleihan, MD, MPH, FRCP (LEB)

Virtual

08:55-09:20

P₄

Osteoporosis in children: update in management

AbdelSalam Abu libdeh, MD (PAL)

Virtual

09:20-09:45

P₅

Osteoporosis management: clinical cases

Ghada El-Hajj Fuleihan, MD, MPH, FRCP (LEB)

Virtual

09:45-10:10

P₆

Glucocorticoid Induced Osteoporosis

Nadim Jarrah, MD (JOR)

10:10-10:20

Q&A

10:20-10:30

Coffee Break



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SESSION 3 Pediatrics

Moderators: Omar Malkawi, MD - Enas Younis, MD - Rasha Odeh, MD - Hala Oweineh, MD

10:30-10:55 **P₇** Subclinical hypothyroidism in childhood, to treat or not to treat.
Rasha Tarif, MD (EGY)

10:55-11:20 **P₈** Use of technology in type 1 DM : management update
Nancy El Barbary, MD (EGY)  **Virtual**

11:20-11:45 **P₉** Delayed Puberty: Update
Rasha Tarif, MD (EGY)

11:45-12:05 **S₆** The Diabetes continuum: from prevention to treatment
Rami Salameh, MD (JOR) 

12:05-12:15 Q&A

12:30-14:00 Friday prayer and lunch



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PHARMA SESSION 3

Moderators: Ahmad Kheir, MD - Omar Abu Hijleh, MD - Fares Haddad, MD - Sima Kalaldeh, MD

- 14:00-14:20 **S₇** Intensification with SGLT2-I: A Paradigm shift to Comprehensive T2D Management
Fares Haddad, MD (JOR)
AstraZeneca 
- 14:20-14:40 **S₈** Teen Obesity Treatment
Sima Kalaldeh, MD (JOR)
novo nordisk 
- 14:40-15:00 **S₉** Implementation of T2DM guidelines to overcome inertia of early use of SGLT2 inhibitors
Omar Abu Hijleh, MD (JOR)
Boehringer Ingelheim 
- 15:00-15:20 **S₁₀** Management of Diabetic Dyslipidemia
Ahmad Kheir, MD (JOR)
AstraZeneca 
- 15:20-15:30 Q&A



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SESSION 4

Endocrine Tumors

Moderators: Fawaz Ammari, MD - Mohammad Juma, MD - Susan Eteivi, MD - Zeina Maani, MD

15:30-15:55 **P₁₀** Updates on Neuroendocrine Tumors
Ashley Grossman, MD (UK) **Virtual**

15:55-16:20 **P₁₁** CV manifestations of Pheochromocytoma
Kais Al Balbissi, MD (JOR)

16:20-16:45 **P₁₂** Resistant Pituitary Tumors
Ashley Grossman, MD (UK) **Virtual**

16:45-16:55 Q&A

16:55-17:05 Coffee Break



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SESSION 5

IDERA Research

**Moderators: Charles SAAB, MD - Amal Madanat, MD - Khaldoun Alsarihin, MD - Monzer Saleh, MD
Samy Azar, MD**

- 17:05-17:20 P
13 Questionnaire results: are patients receiving SGLT2I and GLP1 RA when indicated in MENA region
Martine Abi Khalil, MBA,MHM,MSC (LEB) Virtual
- 17:20-17:35 P
14 Thyroid and pregnancy: place for research
Ali Bernard Khalil, MD (LEB) Virtual
- 17:35-17:50 P
15 Small fiber neuropathy and autonomic dysfunction detected by noninvasive method
Delman Al Attar, MD (IRAQ) Virtual
- 17:50-18:10 P
16 New guidelines for Cardiometabolic management for MENA patient assessment
Mohamad Hassanein, MD (EGY) Virtual
- 18:10-18:20 Q&A
- 19:00** **Dinner**



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PHARMA SESSION 4

Moderators: Nadima Shegem, MD - Yahya Azzam, MD - Musa Abu-Jbara, MD - Firas Annabi, MD

08:30-08:50

S₁₁

Degludec insulin across diverse patients populations

Musa Abu-Jbara, MD (JOR)



08:50-09:10

S₁₂

Role of DPP4i in defining simplicity in managing type 2 DM Focus on linagliptin

Firas Annabi, MD (JOR)



09:10-09:30

S₁₃

Glycemic control: A Major pillar in the treatment of type 2 DM

Nadima Shegem, MD (JOR)



09:30-09:50

S₁₄

Resistant Hypertension from Diagnosis to Management

Ramzi Tabbalat, MD (JOR)



09:50-10:00

Q&A

10:00-10:10

Coffee Break



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SESSION 6

DM / METABOLIC

**Moderators: Ahmad Al Omari, MD - Hisham Jarbou, MD - Jamal Darawsheh, MD
 Subhi Abu Sunbol, MD**

- 10:10-10:35 P
17 Decoding immune suppression in people with diabetes
Joud Jarrah, MD (JOR)
- 10:35-11:00 P
18 Diabetic kidney disease: results from a sample of Jordanian patients
Randa Farah, MD (JOR)
- 11:00-11:25 P
19 Bariatric surgery in adolescence: What is the evidence
Osama Hamid, MD (JOR)
- 11:25-11:35 Q&A



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SESSION 7 Research Oral Presentations

**Moderators: Mureis Barham, MD - Nisreen Saadeh, MD - Rania Al-Asad, MD - Hiba Abbasi, MD
Dina Zaqqa, MD - Lama Shahin, MD**

- 11:35-11:50 P
20 PACT MEA Study
Firas Annabi, MD (JOR)
- 11:50-12:05 P
21 The First Jordanian Dyslipidemia Management Guidelines
Eyas Almousa, MD (JOR)
- 12:05-12:20 P
22 Genetic mutations predicting thyroxine dosage requirements in a sample of hypothyroid patients
Luay Abu-Qatouseh, PhD (JOR)
- 12:20-12:35 P
23 Use of point of care ketone measurement and SC insulin use for prevention and management of DKA
Khubaib Ayoub, MD (PAL) 👤 Virtual
- 12:35-12:50 P
24 Cushing's Syndrome: In depth Analysis of a Factitious Presentation
Ala Attawneh, MD (PAL) 👤 Virtual
- 12:50-13:00 Q&A
- 13:00-13:10 Coffee Break**



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PHARMA SESSION 5

**Moderators: Jihad Haddad, MD - Rula Goussous, MD - Amjad Shdeifat, MD
 Mohammad Ghannam, MD - Musadaq Hamza, MD**

- 13:10-13:30  Role of Finrenone in Managing Patients with CKD and T2D
Hiba Barghouthi, MD (JOR) 
- 13:30-13:50  The role of DPP4I in management of type 2 diabetes
Amjad Shdeifat, MD (JOR) **hikma.**
- 13:50-14:10  Act Now For Your Dyslipidemia Patients
Osama Okkeh, MD (JOR) **ULFA PHARMA CO.**
- 14:10-14:30  GLP-1 in type 2 diabetes
Rula Goussous, MD (JOR) 



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14:30-14:50



DPP-4 Inhibitors: The Power to Control & Protect

Jihad Haddad, MD (JOR)



14:50-15:10



Leqvio: Transforming Atherosclerotic cardiovascular diseases (ASCVD) patients' lives

Ayman Hammoudeh, MD (JOR)



15:10-15:20

Q&A and Closing Remarks

15:20-16:30

Lunch



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I have the will
to try diet after diet.
But I still need help
to lose weight and keep it off.

Your partner with obesity has the will.
You can offer them the way.

Saxenda
liraglutid injektion

Abbreviated prescribing information

Saxenda is a weight loss medication for injection in pre-filled syringes. **Qualitative and quantitative composition** 1 mL of solution contains 6 mg of liraglutid. One pre-filled syringe contains 18 mg liraglutid in 3 mL. **Therapeutic indications** Saxenda[®] is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial body mass index (BMI) of ≥30 kg/m² (obese), or ≥27 kg/m² to ≥30 kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dyslipidaemia (lipid type 2 diabetes mellitus, hypertension, dyslipidaemia or obstructive sleep apnoea). Treatment with Saxenda[®] should be discontinued after 12 weeks on the 3.0 mg daily dose if patients have not lost at least 5% of their initial body weight. **Contraindications** (≥2 years Saxenda[®]) can be used as an adjunct to a healthy diet and increased physical activity for weight management in adult patients from the age of 12 years and above with obesity (BMI corresponding to ≥30 kg/m² for adults by international classification of diseases and body weight above 40 kg). Treatment with Saxenda[®] should be discontinued and re-evaluated if patients have not lost at least 4% of their BMI or BMI z score after 12 weeks on the 3.0 mg/day or maximum tolerated dose. **Precautions** The starting dose is 0.6 mg once daily. The dose should be increased to 3.0 mg once daily in increments of 0.6 mg up to at least once-weekly injections to improve gastro-intestinal tolerability. If escalation to the next dose step is not tolerated for two consecutive weeks, consider discontinuing treatment. Daily doses higher than 3.0 mg are not recommended. **For adolescents from the age of 12 to below 18 years old** a similar dose escalation schedule as for adults should be applied. The dose should be increased until 3.0 mg (maximum dose) or maximum tolerated dose has been reached. Daily doses higher than 3.0 mg are not recommended. **Patients with type 2 diabetes mellitus** Saxenda[®] should not be used in combination with another GLP-1 receptor agonist. When initiating Saxenda[®], consider reducing the dose of concomitantly administered insulin or insulin secretagogues (such as sulfonylureas) to reduce the risk of hypoglycaemia. Liked above self-monitoring is necessary to adjust the dose of insulin or insulin secretagogues. **Special populations** Patients 20 years of age or older: No dose adjustment is required based on age. Therapeutic experience in patients ≥70 years of age is limited and use in these patients is not recommended. No dose adjustment is required in patients with mild or moderate renal impairment (creatinine clearance ≥30 mL/min). Saxenda[®] is not recommended for use in patients with severe renal impairment (creatinine clearance <30 mL/min) including patients with end stage renal disease. No dose adjustment is recommended for patients with mild or moderate hepatic impairment. Saxenda[®] is not recommended for use in patients with severe hepatic impairment and should be used cautiously in patients with mild or moderate hepatic impairment. No dose adjustment is required for adolescents from the age of 12 years and above. The safety and efficacy of Saxenda[®] in children below 12 years of age has not been established. **Method of administration** Saxenda[®] is for subcutaneous use only. It must not be administered intravenously or

intramuscularly. Saxenda[®] is administered once daily at any time, independent of meals. It should be injected in the abdomen, thigh or upper arm. The injection site and timing on the changed without dose adjustment. However, it is preferable the Saxenda[®] is injected around the same time of the day when the most convenient time of the day has been chosen. If a dose is missed within 12 hours from when it is usually taken, the patient should take the dose as soon as possible. If more than 12 hours have passed since you should have used Saxenda[®], skip the missed dose and inject your next dose the following day at the usual time. Do not use a double dose or increase the dose on the following day to make up for the missed dose; the patient should not take the missed dose and resume the once-daily regimen with the next scheduled dose. An extra dose or increase in dose should not be taken to make up for the missed dose. **Contraindications** hypersensitivity to liraglutid or to any of the excipients. **Special warnings and precautions for use** Patients with diabetes mellitus Saxenda[®] must not be used as a substitute for insulin. Diabetic ketoacidosis has been reported in insulin-dependent patients after rapid discontinuation or dose reduction of insulin. There is no clinical experience in patients with congestive heart failure New Heart Association (NHA) class I/II and liraglutid is therefore not recommended for use in these patients. The safety and efficacy of liraglutid for weight management have not been established in patients: aged 75 years or more, treated with other products for weight management, with obesity secondary to endocrinologic or eating disorders or to treatment with medicinal products that may cause weight gain, with severe renal impairment, with severe hepatic impairment. Use in these patients is not recommended. As liraglutid for weight management was not investigated in subjects with mild or moderate hepatic impairment, it should be used with caution in these patients. There is limited experience in patients with inflammatory bowel disease and diabetic gastroparesis. Use of liraglutid is not recommended in these patients since it is associated with transient gastrointestinal adverse reactions, including nausea, vomiting and diarrhoea. Pancreatitis: Acute pancreatitis has been observed with the use of GLP-1 receptor agonists. Patients should be informed of the characteristic symptoms of acute pancreatitis. If pancreatitis is suspected, liraglutid should be discontinued if acute pancreatitis is confirmed. Liraglutid should not be resumed. Cholelithiasis and cholecystitis in clinical trials for weight management, a higher rate of cholelithiasis and cholecystitis was observed in patients treated with liraglutid than in patients on placebo. The fact the substantial weight loss can increase the risk of cholelithiasis and thereby cholecystitis only partially, did not offset the higher rate with liraglutid. Cholelithiasis and cholecystitis may lead to hospitalisation and cholecystectomy. Patients should be informed of the characteristic symptoms of cholelithiasis and cholecystitis. Thyroid disease in clinical trials in type 2 diabetes, thyroid adverse events, such as goitre have been reported in patients in patients with pre-existing thyroid disease. Liraglutid should therefore be used with caution in patients with thyroid disease. Heart rate: An increase in heart rate was observed with liraglutid in clinical trials. Heart rate should be monitored at regular intervals consistent with usual

clinical practice. Patients should be informed of the symptoms of increased heart rate (palitations or feelings of a racing heart beat) but rest. For patients who experience a clinically relevant sustained increase in resting heart rate, treatment with liraglutid should be discontinued. Dehydration Signs and symptoms of dehydration, including renal impairment and acute renal failure, have been reported in patients treated with GLP-1 receptor agonists. Patients treated with liraglutid should be advised on the potential risk of dehydration in relation to gastrointestinal side effects and take precautions to avoid fluid depletion. Patients with type 2 diabetes mellitus receiving liraglutid in combination with insulin and/or sulphonylurea may have an increased risk of hypoglycaemia. The risk of hypoglycaemia may be lowered by a reduction in the dose of insulin and/or sulphonylurea. Episodes of clinically significant hypoglycaemia have been reported in non-diabetic (≥2 years) treated with liraglutid. Patients should be informed about the characteristic symptoms of hypoglycaemia and the appropriate actions. In patients with diabetes mellitus Saxenda must not be used as a substitute for insulin. Diabetic ketoacidosis has been reported in insulin-dependent patients after rapid discontinuation or dose reduction of insulin. **Interaction with other medicinal products and other forms of interaction** In vitro, liraglutid has shown very low potential to be involved in pharmacokinetic interactions with other active substances related to cytochrome P450 (CYP) and plasma protein binding. The small delay of gastric emptying with liraglutid may influence absorption of concomitantly administered oral medicinal products. Interaction studies did not show any clinically relevant delay of absorption and therefore no dose adjustment is required. Interaction studies have been performed with 1.6 mg liraglutid. The effect on rate of gastric emptying was equivalent between liraglutid 1.6 mg and 3.0 mg (see section 4.2). In patients treated with liraglutid reported at least one episode of severe diarrhoea. Diarrhoea may affect the absorption of concomitant oral medicinal products. **Warfarin** and other coumarin derivatives No interaction study has been performed. A clinically irrelevant interaction with active substances with poor solubility or narrow therapeutic index such as warfarin cannot be excluded. Upon initiation of liraglutid treatment in patients on warfarin or other coumarin derivatives more frequent monitoring of international Normalized Ratio (INR) is recommended. **Pregnancy** There are limited data from the use of liraglutid in pregnant women. Studies in animals have shown reproductive toxicity. The potential risk for humans is unknown. Liraglutid should not be used during pregnancy. If a patient wishes to become pregnant, or pregnancy occurs, treatment with liraglutid should be discontinued. **Breast-feeding** It is not known whether liraglutid is excreted in human milk. Animal studies have shown that the transfer of liraglutid and metabolites of liraglutid into milk is low. Because of lack of experience, Saxenda[®] should not be used during breastfeeding. **Fertility** apart from a slight decrease in the number of live offspring, animal studies did not indicate harmful effects with respect to fertility. **Effects on ability to drive and use machines** Power, dizziness can be experienced mainly during

the first 3 months of treatment with Saxenda. Driving or use of machines should be avoided with caution if dizziness occurs. **Undesirable effects** Adverse reactions are listed respectively by frequency. Frequency categories are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (≥1/100,000). Within each frequency group, adverse reactions are presented in order of decreasing seriousness. **Very common**: Headache, Nausea, vomiting, diarrhoea, constipation. **Common**: hypoglycaemia, insomnia, dizziness, dyspnoea, dry mouth, dyslipidaemia, gastritis, gastro-oesophageal reflux disease, abdominal pain upper, flatulence, eructation, abdominal distension, cholelithiasis, injection site reactions, asthma, fatigue, increased lipase, increased amylase. **Uncommon**: dehydration, tachycardia, pancreatitis, gallstone, emptying cholecystitis, urticaria, malaise. **Rare**: hypoglycaemia, acute renal failure, renal impairment, increased creatinine. **Very rare**: acute pancreatitis. **Diabetic ketoacidosis** has been reported in insulin-dependent patients after rapid discontinuation or dose reduction of insulin. **For more details on selected adverse reactions please refer to the full SMI. Overdose** From clinical trial and post-marketing use of liraglutid overdoses have been reported up to 12 mg/24 times the recommended dose for weight management. Events reported included severe nausea, severe vomiting and severe hypoglycaemia. In the event of overdose, appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms. The patient should be observed for clinical signs of hypoglycaemia and blood glucose should be monitored. **List of excipients** Disodium phosphate dihydrate, propylene glycol, phenol, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment), water for injections. **Incompatibilities** Substances added to Saxenda may cause degradation of liraglutid. In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products. **Special precautions for storage** Store in a refrigerator (2°C - 8°C). Do not freeze. Store away from the freezer. After first use: Store below 30°C or store in a refrigerator (2°C - 8°C). **Shelf life** 30 months. After first use: 1 month. The product should be discarded 1 month after first use. Keep the cap on the pen in order to protect from light. **Special precautions for disposal and other handling** The solution should not be used if it does not appear clear, colourless or almost colourless. Saxenda[®] should not be used if it has been frozen. The pen is designed to be used with NovoPen[®] or NovoPen[®] disposable needles up to a length of 8 mm and as thin as 32G. Needles are not included in the pack. The patient should be advised to discard the injection needle after each injection and store the pen without an injection needle attached. This prevents contamination, infection and leakage. It also ensures that the dosing is accurate. Any unused medicinal product or waste material should be disposed in accordance with local requirements. **Marketing authorisation holder**: Novo Nordisk A/S, Novo Nordisk, DK-2860 Søborg, Denmark. Refer to the Summary of Product Characteristics before prescribing. Based on PARSAP dated Sep 2021. Code: 2023/000004

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For reporting side effects, please note the below
JPA's side effects reporting: #side
E-mail: jpa@sidea.se
Electronic reporting on JPA's website: www.jpa.com
www.novonordisk.com
Telephone number: +46 9 6362000



SARAH, Age: 43 BMI: 37

102300001

Saxenda
liraglutid injektion

APPROVED for
adolescents aged 12-17.¹

Saxenda[®]
liraglutide injection

Weight management for **THE NEXT GENERATION**

Now, you can help with Saxenda[®], approved prescription medication for weight management in adolescents.¹

80% of adolescents with obesity will continue to have obesity in adulthood if left untreated.²

Patient portrayals.

Prescribe Saxenda[®], and give adolescents the support they need to help manage their weight

Reference:
1. Saxenda[®] (liraglutide injection) [USDA] - 2019. 2. Obesity in Children and Adolescents. WHO. 2015.

Saxenda[®] (liraglutide injection) is a prescription medication for weight management in adolescents aged 12-17 years. The safety and efficacy of Saxenda[®] in adolescents is based on clinical studies conducted in adolescents aged 12-17 years. Saxenda[®] is not approved for use in children aged 6-11 years or in children aged 12-17 years who are not overweight or obese. Saxenda[®] is not approved for use in adolescents aged 18 years and older. For more information, visit www.saxenda.com. © 2021 Novo Nordisk. All rights reserved. Novo Nordisk, Saxenda, and the Novo Nordisk logo are trademarks of Novo Nordisk. Novo Nordisk is not responsible for the content of this advertisement.

Saxenda[®] (liraglutide injection) is a prescription medication for weight management in adolescents aged 12-17 years. The safety and efficacy of Saxenda[®] in adolescents is based on clinical studies conducted in adolescents aged 12-17 years. Saxenda[®] is not approved for use in children aged 6-11 years or in children aged 12-17 years who are not overweight or obese. Saxenda[®] is not approved for use in adolescents aged 18 years and older. For more information, visit www.saxenda.com. © 2021 Novo Nordisk. All rights reserved. Novo Nordisk, Saxenda, and the Novo Nordisk logo are trademarks of Novo Nordisk. Novo Nordisk is not responsible for the content of this advertisement.

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I have the will
to try diet after diet.
But I still need help
to lose weight and keep it off.

Your partner with obesity has the will.
You can offer them the way.

Saxenda
liraglutid injektion

Abbreviated prescribing information

Saxenda (liraglutid) is indicated for injection in pre-diabetic patients. **Qualitative and quantitative composition** 1 mL of solution contains 6 mg of liraglutid. One pre-filled pen-injector (18 mL) of Saxenda contains 108 mg of liraglutid. **Therapeutic indications** Saxenda[®] is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial body mass index (BMI) of ≥30 kg/m² (obese), or ≥27 kg/m² to ≥30 kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dyslipidaemia (lipid levels in type 2 diabetes mellitus, hypertension, dyslipidaemia or obstructive sleep apnoea). Treatment with Saxenda[®] should be discontinued after 12 weeks on the 3.0 mg daily dose if patients have not lost at least 5% of their initial body weight. **Adults (≥12 years)** Saxenda[®] can be used as an adjunct to a healthy diet and increased physical activity for weight management in adult patients from the age of 12 years and above with obesity (BMI corresponding to ≥30 kg/m² for adults by international classification of diseases and body weight above 40 kg). Treatment with Saxenda[®] should be discontinued and re-evaluated if patients have not lost at least 4% of their BMI or BMI z score after 12 weeks on the 3.0 mg/day or maximum tolerated dose. **Paediatric** The starting dose is 0.6 mg once daily. The dose should be increased to 3.0 mg once daily in increments of 0.6 mg up to at least once-weekly injections to improve gastro-intestinal tolerability. If escalation to the next dose step is not tolerated for two consecutive weeks, consider discontinuing treatment. Daily doses higher than 3.0 mg are not recommended. **For adolescents from the age of 12 to below 18 years** data is similar to dose escalation schedule as for adults should be applied. The dose should be increased until 3.0 mg (maximum dose) or maximum tolerated dose has been reached. Daily doses higher than 3.0 mg are not recommended. **Patients with type 2 diabetes mellitus** Saxenda[®] should not be used in combination with another GLP-1 receptor agonist. When initiating Saxenda[®], consider reducing the dose of concomitantly administered insulin or insulin secretagogues (such as sulfonylureas) to reduce the risk of hypoglycaemia. Liked above sub-therapeutic is necessary to adjust the dose of insulin or insulin secretagogues. **Special populations** Patients 18 years and 60 No dose adjustment is required based on age. Therapeutic experience in patients ≥70 years of age is limited and use in these patients is not recommended. No dose adjustment is required in patients with mild or moderate renal impairment (creatinine clearance ≥30 mL/min). Saxenda[®] is not recommended for use in patients with severe renal impairment (creatinine clearance <30 mL/min) including patients with end stage renal disease. No dose adjustment is recommended for patients with mild or moderate hepatic impairment. Saxenda[®] is not recommended for use in patients with severe hepatic impairment and should be used cautiously in patients with mild or moderate hepatic impairment. No dose adjustment is required for adolescents from the age of 12 years and above. The safety and efficacy of Saxenda[®] in children below 12 years of age has not been established. **Method of administration** Saxenda[®] is for subcutaneous use only. It must not be administered intravenously or

intramuscularly. Saxenda[®] is administered once daily at any time, independent of meals. It should be injected in the abdomen, thigh or upper arm. The injection site and timing on the changed without dose adjustment. However, it is preferable the Saxenda[®] is injected around the same time of the day when the most convenient time of the day has been chosen. If a dose is missed within 12 hours from when it is usually taken, the patient should take the dose as soon as possible. If more than 12 hours have passed since you should have used Saxenda[®], skip the missed dose and inject your next dose the following day at the usual time. Do not use a double dose or increase the dose on the following day to make up for the missed dose. The patient should not take the missed dose and resume the once-daily regimen with the next scheduled dose. An extra dose or increase in dose should not be taken to make up for the missed dose. **Contraindications** hypersensitivity to liraglutid or to any of the excipients. **Special warnings and precautions for use** Patients with diabetes mellitus Saxenda[®] must not be used as a substitute for insulin. Diabetic ketoacidosis has been reported in insulin-dependent patients after rapid discontinuation or dose reduction of insulin. There is no clinical experience in patients with congestive heart failure New Heart Association (NHA) class I/II and liraglutid is therefore not recommended for use in these patients. The safety and efficacy of liraglutid for weight management have not been established in patients: aged 75 years or more, treated with other products for weight management, with obesity secondary to endocrinopathy or eating disorders or to treatment with medicinal products that may cause weight gain, with severe renal impairment, with severe hepatic impairment. Use in these patients is not recommended. As liraglutid for weight management was not investigated in subjects with mild or moderate hepatic impairment, it should be used with caution in these patients. There is limited experience in patients with inflammatory bowel disease and diabetic gastroparesis. Use of liraglutid is not recommended in these patients since it is associated with transient gastrointestinal adverse reactions, including nausea, vomiting and diarrhoea. Pancreatitis: Acute pancreatitis has been observed with the use of GLP-1 receptor agonists. Patients should be informed of the characteristic symptoms of acute pancreatitis. If pancreatitis is suspected, liraglutid should be discontinued if acute pancreatitis is confirmed. Liraglutid should not be resumed. Cholelithiasis and cholecystitis in clinical trials for weight management, a higher rate of cholelithiasis and cholecystitis was observed in patients treated with liraglutid than in patients on placebo. The fact that substantial weight loss can increase the risk of cholelithiasis and thereby cholecystitis only partially offsets the higher rate with liraglutid. Cholelithiasis and cholecystitis may lead to hospitalisation and cholecystectomy. Patients should be informed of the characteristic symptoms of cholelithiasis and cholecystitis. Thyroid disease in clinical trials in type 2 diabetes, thyroid adverse events, such as goitre have been reported in patients in patients with pre-existing thyroid disease. Liraglutid should therefore be used with caution in patients with thyroid disease. Heart rate: An increase in heart rate was observed with liraglutid in clinical trials. Heart rate should be monitored at regular intervals consistent with usual

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Telephone reporting on JORDAN website: www.jordan.novonordisk.com
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Telephone number: +962 5 961 52000



SARAH, Age: 43 BMI: 37

the first 3 months of treatment with Saxenda. Driving or use of machines should be avoided with caution if dizziness occurs. **Undesirable effects** Adverse reactions are listed respectively by frequency. Frequency categories are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (≥1/100,000). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness. **Very common**: Headache, Nausea, vomiting, diarrhoea, constipation. **Common**: hypoglycaemia, insomnia, dizziness, dyspnoea, dry mouth, dyslipidaemia, gastritis, gastro-oesophageal reflux disease, abdominal pain upper, flatulence, eructation, abdominal distension, cholelithiasis, injection site reactions, asthma, fatigue, increased lipase, increased amylase. **Uncommon**: dehydration, tachycardia, pancreatitis, gallstone, emptying cholecystitis, urticaria, malaise. **Rare**: hypoglycaemia, hypokalaemia, acute renal failure, renal impairment. **Very rare**: acute pancreatitis. **For more details on selected adverse reactions please refer to the full SMI. Overdose** From clinical trial and post-marketing use of liraglutid overdoses have been reported up to 12 mg/24 times the recommended dose for weight management. Events reported included severe nausea, severe vomiting and severe hypoglycaemia. In the event of overdose, appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms. The patient should be observed for clinical signs of hypoglycaemia and blood glucose should be monitored. **List of excipients** Disodium phosphate dihydrate, propylene glycol, phenol, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment), water for injections. **Incompatibilities** Substances added to Saxenda may cause degradation of liraglutid. In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products. **Special precautions for storage** Store in a refrigerator (2°C - 8°C). Do not freeze. Store away from the freezer. After first use: Store below 30°C or store in a refrigerator (2°C - 8°C). **Shelf life** 30 months. After first use: 1 month. The product should be discarded 1 month after first use. Keep the cap on the pen in order to protect from light. **Special precautions for disposal and other handling** The solution should not be used if it does not appear clear, colourless or almost colourless. Saxenda[®] should not be used if it has been frozen. The pen is designed to be used with NovoPen[®] or NovoPen[®] disposable needles up to a length of 8 mm and as thin as 32G. Needles are not included in the pack. The patient should be advised to discard the injection needle after each injection and store the pen without an injection needle attached. This prevents contamination, infection and leakage. It also ensures that the dosing is accurate. Any unused medicinal product or waste material should be disposed in accordance with local requirements. **Marketing authorisation holder**: Novo Nordisk A/S, Novo Nordisk, DK-2860 Søborg, Denmark. Refer to the Summary of Product Characteristics before prescribing. Based on PARSAP dated Sep 2021. Code: J023300004

Saxenda
liraglutid injection

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