Novo Nordisk Invitation

Rybelsus®▼ (Semaglutide Tablets) Lunchtime Update for Community Pharmacists

Tuesday 2nd November 2021

(Virtual meeting)

This meeting is for UK healthcare professionals only.

Agenda

12:15	**Registration**
12:30	**Welcome & Introduction** **Victoria Ruszala - Specialist Pharmacist**
12:35	**Rybelsus®▼ (Semaglutide Tablets) The First Oral GLP1-RA, how does it work?** **Dr Eddy Candy - Senior Regional Medical Advisor Novo Nordisk**
13:00	**Rybelsus®▼ (Semaglutide Tablets) Patient Experience Case Studies** **Sharon Tovey - Senior Research Nurse**
13:15	**The Role of the Community Pharmacist** **Victoria Ruszala - Specialist Pharmacist**
13:30	**Meeting Close**

Interested in attending this meeting? RSVP to:

To RSVP
Scan Here

Robert Rawlinson
NHS Partnerships Manager
rraw@novonordisk.com
07769 234744
Please respond by Thursday 30th September 2021

RRAW/LPC21

This meeting is organised and funded by Novo Nordisk.

Please find Rybelsus®▼ prescribing information overleaf.

Prescribing Information

Rybelsus® ▼
tablets
semaglutide

Rybelsus® 3 mg tablets
Rybelsus® 7 mg tablets
Rybelsus® 14 mg tablets

Indications: Rybelsus® is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise

- as monotherapy when metformin is considered inappropriate due to intolerance or contraindications
- in combination with other medicinal products for the treatment of diabetes.

For study results with respect to combinations, effects on glycaemic control and cardiovascular events, and the populations studied, see sections 4.4, 4.5 and 5.1 of the SmPC.

Posology and administration: Administered once daily for oral use, should be taken on an empty stomach at any time of the day. The tablet should be swallowed whole with a sip of water (up to 120 ml). Tablets should not be split, crushed or chewed. The patient should wait at least 30 minutes before eating, drinking or taking other oral medicine. The starting dose of semaglutide is 3 mg once daily for 1 month. After 1 month the dose should be increased to a maintenance dose of 7 mg once daily. After at least 1 month with 7 mg the dose can be increased to a maintenance dose of 14 mg once daily to further improve glycaemic control. The maximum recommended single daily dose is 14 mg. Taking two 7 mg tablets to achieve the effect of a 14 mg dose has not been studied and is not recommended. If a dose is missed, the missed dose should be skipped and the next dose taken the following day. When semaglutide is used in combination with metformin and/or a sodium-glucose co-transporter-2 inhibitor (SGLT2i) or thiazolidinedione the current dose of metformin and/or SGLT2i or thiazolidinedione can be continued. Children & adolescents below 18 years: No data are available. Elderly: No dose adjustment, therapeutic experience in patients ≥75 is limited. Renal Impairment: No dose adjustment is required for patients with mild, moderate or severe renal impairment. Experience in patients with severe renal impairment is limited. Not recommended for use in patients with end-stage renal disease. Hepatic impairment: No dose adjustment is required for patients with hepatic impairment. Experience with severe hepatic impairment is limited. Caution should be exercised when treating these patients with semaglutide.

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Special warnings and precautions for use: In order to improve traceability of biological medicinal products, the name and batch number of the administered product should be clearly recorded. Semaglutide should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Diabetic ketoacidosis has been reported in insulin-dependent patients whom had rapid discontinuation or dose reduction of insulin when treatment with a GLP-1 receptor agonist is started. Use of semaglutide in combination with a sulfonylurea or insulin may have an increased risk of hypoglycaemia. The risk of hypoglycaemia can be lowered by reducing the dose of sulfonylurea or insulin when initiating treatment with semaglutide. Blood glucose self-monitoring is necessary to adjust the dose of sulfonylurea and insulin, particularly when semaglutide is started and insulin is reduced. A stepwise approach to insulin reduction is recommended. Patients should be advised to take precautions to avoid hypoglycaemia while driving and using machines. There is no experience in patients with congestive heart failure NYHA class IV and is therefore not recommended in these patients. Use of GLP-1 receptor agonists may be associated with gastrointestinal adverse reactions that can cause dehydration, which in rare cases can lead to a deterioration of renal function. Patients treated with semaglutide should be advised of the potential risk of dehydration in relation to gastrointestinal side effects/take precautions to avoid fluid depletion. 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, semaglutide should be discontinued; if confirmed, semaglutide should not be restarted. Caution should be exercised when using semaglutide in patients with a history of pancreatitis. In patients with diabetic retinopathy treated with insulin and s.c. semaglutide, an increased risk of developing diabetic retinopathy complications has been observed, a risk that cannot be excluded for oral semaglutide. Caution should be exercised when using oral semaglutide in patients with diabetic retinopathy. These patients should be monitored closely and treated according to clinical guidelines. Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy, but other mechanisms cannot be excluded. Compliance with the dosing regimen is recommended for optimal effect. If the treatment response is lower than expected, the physician should be aware that the absorption of semaglutide is highly variable and may be minimal and the absolute bioavailability is low. Oral semaglutide contains 23 mg sodium per tablet, equivalent to 1% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Fertility, pregnancy and lactation: Women of childbearing potential are recommended to use contraception when treated with semaglutide. Should not be used during pregnancy or breast-feeding. Discontinue at least 2 months before a planned pregnancy. Effect on fertility unknown.

Undesirable effects: Adverse events in clinical trials which could be considered **serious** include:
(≥1/10)**:** Hypoglycaemia when used with insulin or sulfonylurea
(≥1/100 to <1/10): Diabetic retinopathy complications
(≥1/1,000 to <1/100): Cholelithiasis
(≥1/10,000 to <1/1,000): Anaphylactic reaction, acute pancreatitis
(<1/10,000): N/A
Other **Very common** (≥1/10: Nausea, diarrhoea
Other **Common** (≥1/100 to <1/10): Hypoglycaemia when used with other OADs, decreased appetite, vomiting, abdominal pain, abdominal distension, constipation, dyspepsia, gastritis, gastro-oesophageal reflux disease, flatulence, fatigue, increased lipase, increased amylase.
Of medical interest: Increased heart rate

MA numbers and Basic NHS Price:
Rybelsus® 3 mg x 30 tablets, EU/1/20/1430/2, £78.48
Rybelsus® 7 mg x 30 tablets, EU/1/20/1430/5, £78.48
Rybelsus® 14 mg x 30 tablets, EU/1/20/1430/8, £78.48
Legal category: POM.

For full prescribing information please refer to the **SmPC** which can be obtained from: Novo Nordisk Limited, 3 City Place, Beehive Ring Road, Gatwick, W. Sussex, RH6 0PA.
Marketing Authorisation Holder: Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark.

Date last revised: October 2020

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
Adverse events should also be reported to Novo Nordisk Limited (Telephone Novo Nordisk Customer Care Centre 0845 6005055). Calls may be monitored for training purposes.