CPD MODULE

Certificate of participation

Has completed the online CPD module entitled:

Introducing and using the BYDUREON BCise (exenatide) device

Date:

Number of hours: 1.0

This promotional information has been initiated, created, funded and reviewed by AstraZeneca.

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PRESCRIBING INFORMATION

BYDUREON® (exenatide) 2MG POWDER AND SOLVENT FOR PROLONGED-RELEASE SUSPENSION FOR INJECTION IN PRE-FILLED PEN (DUAL CHAMBER PEN)

BYDUREON® (exenatide) 2MG PROLONGED-RELEASE SUSPENSION FOR INJECTION IN PRE-FILLED PEN (BCISE)

Please note this is a combined PI for BYDUREON Dual Chamber Pen and Bydureon BCise;
Consult Summary of Product Characteristics before prescribing.

Indication: Adults 18 years and older: For patients with type 2 diabetes mellitus to improve glycaemic control in combination with other glucose-lowering medicinal products including basal insulin, when the therapy in use, together with diet and exercise, does not provide adequate glycaemic control.

Presentation:
Dual Chamber Pen: Powder and solvent for prolonged-release suspension for injection containing 2mg exenatide.
BCise: Prolonged-release suspension for injection containing 2mg exenatide.

Dosage and Administration: Adults: The recommended dose is 2mg exenatide once weekly, on the same day each week, at any time of day, with or without meals. Administer as subcutaneous injection in the thigh, abdomen, or back of the upper arm immediately after suspension of powder in the solvent and when the product is fully mixed. If a dose is missed, administer as soon as practical, provided the next dose is due in 3 days or more. Thereafter, resume a once weekly dosing schedule. Prolonged-release exenatide is for self-administration and for single use only, appropriate training is recommended. Administer prolonged-release exenatide and insulin as two separate injections. Patients switching from immediate-release to prolonged-release exenatide may experience transient elevations in blood glucose concentrations, which generally improve within first two weeks (Dual Chamber Pen) and first four weeks (BCise) after therapy initiation. Patients switching between Dual Chamber Pen and BCise may do so with no expected relevant effect on blood glucose levels. When prolonged-release exenatide is added to existing metformin and/or thiazolidinedione therapy, the current dose of these oral therapies can be continued. When added to sulphonylurea therapy, a reduction in the dose of sulphonylurea should be considered to reduce the risk of hypoglycaemia. Blood glucose self-monitoring is necessary to adjust the dose of sulphonylurea and of insulin, particularly when prolonged-release exenatide therapy is started and insulin is reduced. A stepwise approach to insulin dose reduction is recommended. If a different glucose-lowering treatment is started after the discontinuation of prolonged-release exenatide, consideration should be given to the prolonged release of the product. **Elderly:** No dose adjustment required. Consideration should be given to the patient's renal function. **Renal or hepatic impairment:** No dose adjustment required for patients with hepatic impairment, mild or moderate renal impairment. Not recommended in patients with severe renal impairment (glomerular filtration rate [GFR] <30 mL/min) or end-stage renal disease. **Paediatric population:** <18 years old: Safety and efficacy not established.

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

Warnings and Precautions: Not to be used in patients with type 1 diabetes mellitus, diabetic ketoacidosis or as a substitute for insulin. Must not be administered by intravenous or intramuscular injection. **Renal impairment:** Uncommon events of altered renal function with exenatide, including increase serum creatinine, renal impairment, worsened chronic renal failure and acute renal failure, sometimes requiring haemodialysis. Some occurred in patients experiencing events that may affect hydration and/or receiving medicinal products known to affect renal function/hydration status, including angiotensin converting enzyme inhibitors, angiotensin-II antagonists, non-steroidal anti-inflammatory medicinal products and diuretics. Reversibility observed with supportive treatment and discontinuation of potentially causative medicinal products, including exenatide. **Severe gastrointestinal disease:** Not recommended. **Acute pancreatitis:** Use of GLP-1 receptor agonists has been associated with a risk of developing acute pancreatitis. Acute pancreatitis has been reported spontaneously and in clinical studies. Resolution of pancreatitis has been observed with supportive treatment, but very rare cases of necrotising or haemorrhagic pancreatitis and/or death have been reported. Inform patients of the characteristic symptom of acute pancreatitis: persistent, severe abdominal pain. If pancreatitis suspected, discontinue use; if acute pancreatitis is confirmed, prolonged-release exenatide should not be restarted. Caution should be exercised in patients with a history of pancreatitis. **Concomitant medicinal products:** Concurrent use of prolonged-release exenatide with meglitinides, alpha-glucosidase inhibitors, dipeptidyl peptidase-4 inhibitors or other GLP-1 receptor agonists have not been studied. The concurrent use of prolonged-release and immediate-release exenatide has not been studied and is not recommended. **Weight loss:** Rapid weight loss at a rate of >1.5kg per week has been reported with exenatide, which may have harmful consequences. Monitor for signs and symptoms of cholelithiasis. **Discontinuation of treatment:** The effect of prolonged-release exenatide may continue as plasma levels of exenatide decline over 10 weeks. Consider choice of other medicinal products and dose selection accordingly until exenatide levels decline.

Drug Interactions: No dose adjustment required for medicinal products sensitive to delayed gastric emptying. **Warfarin and cumarol derivatives:** Increased INR (International normalised ratio) sometimes associated with bleeding, spontaneously reported during concomitant use of warfarin and prolonged-release exenatide. Monitor INR during initiation of prolonged-release exenatide. **HMG CoA reductase inhibitors:** Concomitant use with exenatide was not associated with consistent changes in lipid profiles. Monitor lipid profiles as appropriate.

Pregnancy and Lactation: Women of childbearing potential should use contraception during treatment with prolonged-release exenatide. Discontinue at least 3 months before trying to get pregnant. Should not be used during pregnancy and breast-feeding.

Ability to Drive and Use Machines: Prolonged-release exenatide has minor influence on the ability to drive and use machines. Advise patients to take precautions when used in combination with a sulphonylurea to avoid hypoglycaemia.

Undesirable Events: Consult SmPC for full list of side effects.
For Dual Chamber Pen and BCise: **Very common (≥1/10):** Hypoglycaemia (with sulphonylurea). **Common (≥1/100 to <1/10):** Hypoglycaemia (with insulin), dizziness, headache, vomiting, abdominal distention, abdominal pain, dyspepsia, constipation, gastroesophageal reflux disease, injection site pruritus, fatigue, injection site erythema. **Uncommon (≥ 1/1000 to < 1/100):** Dehydration, somnolence, intestinal obstruction, acute pancreatitis, eructation, altered renal function (including acute renal failure, worsened chronic renal failure, renal impairment, increased serum creatinine), injection site rash, alopecia, hyperhidrosis, dysgeusia. **Rare (≥1/10,000 to <1/1000):** Anaphylactic reaction, feeling jittery. **Frequency not known:** Drug-induced thrombocytopenia, injection site abscesses and cellulitis, INR ratio increased with concomitant warfarin use (some reports associated with bleeding).
For Dual Chamber Pen: **Very common (≥1/10): D**iarrhoea and nausea. **Common (≥1/100 to <1/10):** Decreased appetite, flatulence, pruritus and/or urticaria and asthenia. **Frequency not known:** Macular and papular rash, angioneurotic oedema.
For BCise: **Common (≥1/100 to <1/10):** Nausea and diarrhoea. **Uncommon (≥ 1/1000 to < 1/100):** Hypoglycaemia (without a sulphonylurea), decreased appetite, flatulence, intestinal obstruction, urticaria, macular or popular rash, pruritus, injection site reaction and asthenia. **Frequency not known:** Angioedema
Patients may develop anti-exenatide antibodies following treatment with prolonged-release exenatide. These patients tend to have more injection site reactions (e.g. skin redness, itching). Small subcutaneous injection site nodules observed very frequently, consistent with the known properties of PLGA polymer microsphere formulations.

Legal Category: POM.

Marketing Authorisation Number: ***Dual Chamber Pen:*** EU/1/11/696/003 (pre-filled pen) ***BCise:*** EU/1/11/696/005 (pre-filled pen).

Presentation & Basic NHS Cost: ***Dual Chamber Pen:*** 4 x 1 pre-filled pen £73.36. ***BCise:*** 4 x 1 pre-filled pen £73.36.

Marketing Authorisation Holder: AstraZeneca AB, SE-151 85 Södertälje, Sweden.

Further Information is Available From: AstraZeneca UK Limited., 600 Capability Green, Luton, LU1 3LU, UK.
Bydureon is a trademark of the AstraZeneca group of companies.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to AstraZeneca by visiting https://aereporting.astrazeneca.com or by calling 0800 783 0033.