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**BYDUREON**® (exenatide)

#### ABBREVIATED PRESCRIBING INFORMATION

**Presentation** Exenatide 2mg powder and solvent for prolonged-release suspension for injection. Each single-dose kit contains one vial of 2mg exenatide and one pre-filled syringe of 0.65ml solvent. **Uses** Bydureon is indicated for treatment of Type 2 diabetes mellitus in combination with metformin, sulphonylureas, thiazolidinediones, or combinations of metformin and a sulphonylurea or metformin and a thiazolidinedione, in patients who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies. **Dosage and Administration** The recommended dose is 2mg once weekly, on the same day each week. Each dose should be administered in the abdomen, thigh, or the back of the upper arm as a subcutaneous injection immediately after suspension of the powder in the solvent. Instructions on the suspension and administration of Bydureon can be found in the 'Instructions for the User' provided in the carton and must be followed carefully by the patient. Appropriate training is recommended for non-healthcare professionals administering the product. Patients switching from exenatide twice daily (Byetta) to Bydureon may experience transient elevations in blood glucose concentrations, which generally improve within the first two weeks after initiation of therapy. When Bydureon is added to existing metformin and/or thiazolidinedione therapy, the current dose of metformin and/or thiazolidinedione can be continued. When Bydureon is added to sulphonylurea therapy, a reduction in the dose of sulphonylurea should be considered to reduce the risk of hypoglycaemia. Blood glucose self-monitoring may be necessary to adjust the dose of sulphonylurea. If a different antidiabetic treatment is started after the discontinuation of Bydureon, consideration should be given to the prolonged release of Bydureon. **Elderly:** No dose adjustment is required based on age. Consideration should be given to the patient's renal function. **Renal or hepatic impairment:** No dosage adjustment is necessary in patients with mild renal impairment (creatinine clearance 50–80ml/min) or hepatic impairment. Not recommended in patients with moderate renal impairment (creatinine clearance 30–50ml/min), severe renal impairment (creatinine clearance <30ml/min), or end-stage renal disease. **Paediatric population:** The safety and efficacy in children and adolescents aged under 18 years have not yet been established. No data are available. **Contraindications** Hypersensitivity to the active substance or to any of the excipients. **Warnings and Special Precautions** Should not be used in patients with Type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Must not be administered by intravenous or intramuscular injection. Not recommended for use in patients with moderate or severe renal impairment or end-stage renal disease. There have been rare, spontaneously reported events of altered renal function with exenatide, including increased serum creatinine, renal impairment, worsened chronic renal failure, and acute renal failure, sometimes requiring haemodialysis. Some of these occurred in patients experiencing events that may affect hydration and/or receiving medicinal products known to affect renal function/hydration status, including angiotensin converting enzymes inhibitors, angiotensin-II antagonists, non-steroidal anti-inflammatory medicinal products, and diuretics. Not recommended in patients with severe gastro-intestinal disease. There have been rare, spontaneously reported events of acute pancreatitis. Patients should be informed of the characteristic symptom of acute pancreatitis: persistent, severe abdominal pain. Resolution of pancreatitis has been observed with supportive treatment, but very rare cases of necrotizing or haemorrhagic pancreatitis and/or death have been reported. If pancreatitis is suspected, Bydureon and other potentially suspect medicinal products should be discontinued. Treatment with Bydureon should not be resumed after pancreatitis has been diagnosed. The concurrent use of Bydureon with insulin, D-phenylalanine derivatives (meglitinides), alpha-glucosidase inhibitors, dipeptidyl peptidase-4 inhibitors, or other GLP-1 receptor agonists has not been studied. The concurrent use of Bydureon and exenatide twice daily (Byetta) has not been studied and is not recommended. The risk of hypoglycaemia was increased when Bydureon was used in combination with a sulphonylurea

in clinical trials. Furthermore, patients on a sulphonylurea combination, with mild renal impairment, had an increased incidence of hypoglycaemia compared to patients with normal renal function. To reduce the risk of hypoglycaemia associated with the use of a sulphonylurea, reduction in the dose of sulphonylurea should be considered. Rapid weight loss (>1.5 kg per week) has been reported in patients treated with exenatide. Weight loss of this rate may have harmful consequences. There have been some reported cases of increased INR, sometimes associated with bleeding, with concomitant use of warfarin and exenatide. After discontinuation, the effect of Bydureon may continue as plasma levels of exenatide decline over 10 weeks. Choice of other medicinal products and dose selection should be considered accordingly until exenatide levels decline. **Interactions** The following interaction studies were conducted using 10 micrograms exenatide twice daily, but not exenatide once weekly: **HMG CoA reductase inhibitors:** Lovastatin AUC and  $C_{max}$  were decreased and  $T_{max}$  was delayed when exenatide (10µg BD) was administered concomitantly with a single dose of lovastatin (40mg). Concomitant use of exenatide twice daily and HMG CoA reductase inhibitors was not associated with consistent changes in lipid profiles. Lipid profiles should be monitored as appropriate. **Warfarin:**  $T_{max}$  was delayed when warfarin was administered 35 min after exenatide twice daily. No clinically relevant effects on  $C_{max}$  or AUC were observed. Increased INR has been reported during concomitant use of warfarin and exenatide twice daily. INR should be monitored during initiation of Bydureon therapy in patients on warfarin and/or cumarol derivatives. **Digoxin and Lisinopril:** A delay in  $T_{max}$  was observed in interaction studies between digoxin or Lisinopril and exenatide twice daily. No clinically relevant effects on  $C_{max}$  or AUC were observed. **Fertility, Pregnancy, and Lactation** Women of childbearing potential should use contraception during treatment with Bydureon. Bydureon should be discontinued at least 3 months before a planned pregnancy. Bydureon should not be used during pregnancy and the use of insulin is recommended. Bydureon should not be used during breast-feeding. **Driving, etc** No studies on the effects on the ability to drive and use machines have been performed. When Bydureon is used in combination with a sulphonylurea, avoid hypoglycaemia while driving and using machines. **Undesirable Effects Adverse Reactions Reported From Clinical Studies Very common:** Hypoglycaemia (with a sulphonylurea), constipation, diarrhoea, nausea, vomiting, injection site pruritus, injection site nodules. **Common:** Decreased appetite, dizziness, headache, abdominal distention, abdominal pain, dyspepsia, eructation, flatulence, gastro-oesophageal reflux, fatigue, injection site erythema, injection site rash, somnolence. Rapid weight loss has been reported with Bydureon. Patients may develop anti-exenatide antibodies following treatment with Bydureon. These patients tend to have more injection site reactions (eg, skin redness, itching). Acute pancreatitis and acute renal failure have been reported rarely and anaphylactic reaction has been reported very rarely in spontaneous post-marketing reports with exenatide twice daily. *For full details of these and other side-effects, please see the Summary of Product Characteristics, which is available at <http://emc.medicines.org.uk/>.* **Legal Category** POM **Marketing Authorisation Number** EU/1/11/696/001 **Basic NHS Cost** £73.36 per 4 weekly pack **Date of Preparation or Last Review** June 2011

#### Full Prescribing Information is Available From

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