BYDUREON is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

• Not recommended as first-line therapy for patients inadequately controlled on diet and exercise
• Not a substitute for insulin, should not be used in patients with type 1 diabetes or diabetic ketoacidosis
• Not recommended for use with insulin
• BYDUREON and BYETTA® (exenatide) injection contain the same active ingredient, exenatide. Do not coadminister with BYETTA
• Not studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis

WARNING: RISK OF THYROID C-CELL TUMORS

• Exenatide extended-release causes an increased incidence in thyroid C-cell tumors at clinically relevant exposures in rats compared to controls. It is unknown whether BYDUREON causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as the human relevance of exenatide extended-release-induced rodent thyroid C-cell tumors has not been determined
• BYDUREON is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC with the use of BYDUREON and inform them of symptoms of thyroid tumors (e.g., mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for detection of MTC in patients treated with BYDUREON

CONTRAINDICATIONS
• Personal or family history of MTC, patients with MEN 2
• Prior serious hypersensitivity reactions to exenatide or product components

WARNINGS AND PRECAUTIONS

• Pancreatitis Exenatide has been associated with acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. After initiation, observe patients carefully for symptoms of pancreatitis. If suspected, discontinue promptly and do not restart if confirmed. Consider other antidiabetic therapies in patients with a history of pancreatitis
• Hypoglycemia BYDUREON increased the risk of hypoglycemia when coadministered with insulin and insulin secretagogues. Consider lowering the dose of these agents when coadministered with BYDUREON
• Renal Impairment Adjusted renal function, including increased serum creatinine, renal impairment, worsening of chronic renal disease, and acute renal failure, sometimes requiring hemodialysis and kidney transplantation has been reported. Not recommended in patients with severe renal impairment or end-stage renal disease. Use caution in patients with renal transplantation or moderate renal failure if this occurs, patients should discontinue BYDUREON
• Severe Gastrointestinal Disease Because exenatide is commonly associated with gastrointestinal adverse reactions, not recommended in patients with severe gastrointestinal disease (e.g., gastroparesis)
• Immunogenicity Patients may develop antibodies to exenatide. In 5 registration trials, attenuated glycometric response was associated in 6% of BYDUREON-treated patients with antibody formation. If worsening of glycemic control occurs, consider alternative antidiabetic therapy
• Hypersensitivity Reports of serious hypersensitivity reactions (e.g., anaphylaxis and angioedema). If anaphylaxis or angioedema occurs, discontinue BYDUREON and promptly seek medical advice
• Injection-Site Reactions Severe reactions (e.g., abscess, cellulitis, and necrosis), with or without subcutaneous nodules, have been reported
• Macrovascular Outcomes No clinical studies establishing conclusive evidence of macrovascular risk reduction with BYDUREON or any other antidiabetic drug

ADVERSE REACTIONS

Most common (≥5%) and occurring more frequently than comparator in clinical trials: nausea (16.9%), diarrhea (12.7%), headache (8.0%), vomiting (6.8%), constipation (5.9%), injection-site pruritus (5.9%), injection-site nodule (5.3%), and dyspepsia (5.1%)

DRUG INTERACTIONS

• Oral Medications BYDUREON slows gastric emptying and may reduce the rate of absorption of orally administered drugs
• Warfarin Increased international normalized ratio (INR) sometimes associated with bleeding has been reported with concomitant use of exenatide with warfarin. Monitor INR frequently until stable upon initiation of BYDUREON

PREGNANT AND NURSING WOMEN

• Pregnant Women Based on animal data, may cause fetal harm. Use during pregnancy only if the potential benefit justifies the potential risk to the fetus. Report drug exposure during pregnancy at 1-800-633-9081
• Nursing Women Discontinue BYDUREON or discontinue nursing

SAVINGS ELIGIBILITY REQUIREMENTS

You may be eligible for this offer if you are insured by commercial insurance and your insurance does not cover the full cost of your prescription, or you are not insured and are responsible for the cost of your prescriptions.

• Patients who are enrolled in a state or federally funded prescription insurance program are not eligible for this offer. This includes patients enrolled in Medicare Part D, Medicaid, Medigap, Veterans Affairs (VA), Department of Defense (DDO) programs or Tricare, and patients who are Medicare eligible and enrolled in an employer-sponsored group waiver health plan or government-subsidized prescription drug benefit program for retirees.
• If you are enrolled in a state or federally funded prescription insurance program, you may not use this savings card even if you elect to be processed as an uninsured (cash paying) patient.
• This offer is not insurance and is restricted to residents of the United States and Puerto Rico. You must be 18 years of age or older.

PROGRAM TERMS OF USE

• Eligible patients with a valid prescription for BYDUREON who present a registered Savings Card at participating pharmacies may be able to pay $25 for their first 3-month (84-day) supply, consisting of either a 28-day initial supply plus 2 refills or 84-day initial supply, followed thereafter by $25 for each 28-day supply for up to 24 months. Maximum savings per each 28-day supply is $100. Offer not applicable to out-of-pocket expenses of $25 or less. Offer valid for up to a total of 26 refills within 24 months, as prescribed. Every year thereafter, patients will be required to renew eligibility.
• Patient must register in the program before redeeming the savings offer. This offer will expire on December 31, 2017.
• Patient must receive a 12-week supply (84-day) of BYDUREON over the first 3 months on BYDUREON prior to claiming a money-back offer.
• The program covers patient out-of-pocket co-pay cost up to a maximum of $100 per 28-day supply.
• Patient must complete the rebate form online at www.12WeekTurnaroundProgram.com within 60 days if they are not satisfied with their progress at the end of their initial 3 months of treatment.
• Non-transferable, limited to one per person, cannot be combined with any other offer. Void where prohibited by law, taxed, or restricted.
• Patients, pharmacists, and prescribers cannot seek reimbursement from health insurance or any government-subsidized prescription drug benefit program for retirees.
• Astrazeneca reserves the right to rescind, revoke, or amend this offer at any time without notice.
• This offer is not conditioned on any past, present, or future purchase, including refills.
• Offer must be presented along with a valid prescription for BYDUREON at the time of purchase. If you have any questions regarding this offer, please call 1-855-687-2069.

BY USING THIS CARD, YOU AND YOUR PHARMACIST UNDERSTAND AND AGREE TO COMPLY WITH THESE ELIGIBILITY REQUIREMENTS AND TERMS OF USE.

MAIL-ORDER INSTRUCTIONS

If you use a mail-order pharmacy (or if your pharmacy does not accept the BYDUREON Savings Card), then follow the steps below:
1. Call your mail-order pharmacy to see if they accept the BYDUREON Savings Card. If they do, provide them with your BYDUREON Savings Card number after they receive your prescription. You will receive your rebate when the pharmacy processes your prescription payment.
2. If your mail-order or retail pharmacy does NOT accept the BYDUREON Savings Card:
   a. Call 1-855-292-5968 to request a patient rebate form, or go to www.patientrebateonline.com to download a form.
   b. When you receive the form, complete and sign it. Next, attach the original mail-order receipt and return it to the address listed on the form.
   c. Remember to keep a copy of your receipts for your records. You should receive your rebate check in 3 to 4 weeks.
   3. You will need to request/download a form each time you get a refill of your prescription and complete steps 2a and 2b to receive your rebate.

Please click here for Medication Guide, and click here for Full Prescribing Information for BYDUREON 2 mg, including Boxed WARNING about possible thyroid tumors including thyroid cancer.