Bydureon® (exenatide) – Product discontinuation

- The FDA announced the permanent discontinuation of AstraZeneca's Bydureon (exenatide) single-dose tray (SDT) formulation.
    - The discontinuation is not due to any safety, efficacy, or quality issues.
    - Bydureon SDT will be available until September 30, 2018.
    - Bydureon Pen and Bydureon® BCise™ will continue to be available.
- Bydureon Pen contains the same formulation and dose as Bydureon SDT. Bydureon BCise contains the same dose of exenatide as Bydureon Pen and Bydureon SDT; however, it uses an oil based diluent.
- Bydureon is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
    - Bydureon is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of the rat thyroid C-cell tumor findings to humans.
    - Bydureon is not a substitute for insulin. Bydureon is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.
    - The concurrent use of Bydureon with prandial insulin has not been established.
    - Bydureon is an extended-release formulation of exenatide. Bydureon should not be used with other products containing the active ingredient exenatide.
    - Bydureon has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- When switching patients from Bydureon SDT to either Bydureon Pen or Bydureon BCise, Bydureon SDT should be discontinued prior to initiation of Bydureon Pen or Bydureon BCise.
- Patients changing from Bydureon SDT to Bydureon Pen or Bydureon BCise may do so at the next regularly scheduled dose.
- Bydureon carries a boxed warning for risk of thyroid C-cell tumors.
- For additional questions, contact AstraZeneca at **1-800-236-9933**.