HIGHLIGHTED INFORMATION FOR PRESCRIBERS
BYDUREON™ (exenatide extended-release for injectable suspension)

This information is being provided as part of the Risk Evaluation and Mitigation Strategy (REMS) plan for BYDUREON. REMS plans have been required for certain drugs with serious risks since 2008 by the U.S. Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh the risks. FDA has determined that a REMS is necessary to ensure that the benefits of BYDUREON outweigh the potential risk of medullary thyroid carcinoma and the risk of acute pancreatitis. Amylin Pharmaceuticals, Inc. has established an informational program for healthcare professionals to help minimize these risks.

There is a Boxed Warning for BYDUREON:

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 human relevance could not be determined by clinical or nonclinical studies. BYDUREON is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Routine serum calcitonin or thyroid ultrasound monitoring is of uncertain value in patients treated with BYDUREON. Patients should be counseled regarding the risk and symptoms of thyroid tumors.

Potential Risk of Medullary Thyroid Carcinoma (MTC)

- Patients with thyroid nodules noted on physical examination or neck imaging should be referred to an endocrinologist for further evaluation.
- Routine monitoring of serum calcitonin (a biomarker of MTC) or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with BYDUREON. Such monitoring may increase the risk of unnecessary procedures, due to the low specificity of serum calcitonin testing for MTC and a high background incidence of thyroid disease.

Risk of Acute Pancreatitis

- Based on postmarketing data exenatide has been associated with acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis.
- After initiation of BYDUREON, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back, which may or may not be accompanied by vomiting).
- If pancreatitis is suspected, BYDUREON should promptly be discontinued, confirmatory tests should be performed, and appropriate management should be initiated.
- If pancreatitis is confirmed, BYDUREON should not be restarted.
- Consider other antidiabetic therapies in patients with a history of pancreatitis.

Appropriate Patient Selection

BYDUREON:

- Is contraindicated in patients with a personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- Is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise.
- Has not been studied in patients with a history of pancreatitis to determine whether these patients are at increased risk for pancreatitis while using BYDUREON. Consider other antidiabetic therapies in patients with a history of pancreatitis.

AMYLIN®

- Should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.
- Has not been studied in combination with insulin and concurrent use is not recommended.
- Should not be used in patients with a history of severe hypersensitivity to exenatide or any product components.

Patients should be informed of the potential risks and benefits of BYDUREON and of alternative modes of therapy.

Patients should be advised to read the Medication Guide before starting BYDUREON and review the information each time their prescription is refilled.

Important Information Regarding a Medullary Thyroid Carcinoma (MTC) Disease Registry

Amylin is establishing a medullary thyroid carcinoma (MTC) case series registry to systematically monitor the annual incidence of MTC in the United States. This study will be designed to identify if there is any increased risk of MTC related to the introduction of BYDUREON into the marketplace and will also characterize patient medical histories related to diabetes and use of BYDUREON.

If you have any questions about the MTC registry, please call 1-877-700-7365 or visit www.BYDUREON.com/REMS.

Indication

The FDA has approved BYDUREON as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

AMYLIN®