Byetta®
exenatide injection

Join us for a discussion on

Improving Glycemic Control When Patients Need It Most

Featuring guest speaker

Sidney A. Jones, MD

Event Details

Friday, November 11, 2011
6:30 PM

Regions Hospital
640 Jackson Street
2nd Floor Amphitheater
Saint Paul, Minnesota 55101

Program Agenda*
6:30 PM Featured presentation

* Welcome & registration starts 30 minutes before featured presentation begins.

To RSVP, please contact:
Rachael Dols 612-232-5687

Space is limited!

RSVP by Monday, November 07, 2011
to ensure your attendance to this event!

Indication and Usage

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

- Not a substitute for insulin and should not be used in patients with type 1 diabetes or diabetic ketoacidosis.
- Concurrent use with insulin cannot be recommended.
- Has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for pancreatitis while using BYETTA; consider other antidiabetic therapies for these patients.

For information about pancreatitis, hypoglycemia, nausea, and the Important Safety Information please see the next pages and the accompanying Prescribing Information and Medication Guide.

*As of January 1, 2011, if you are a US medical doctor or doctor of osteopathy with an active state license number, the value of the meal that you receive when attending this program may be disclosed on Eli Lilly and Company's Physician Payment Registry as a transfer of value made to you by Lilly. As a result of enacted state regulations, individuals with prescribing authority in the state of **Minnesota who have exceeded their $50 per year allocation** will not be provided food/beverage/meals. This medical presentation is intended only for invited Health Care Professionals for whom the information to be presented is relevant to their practice. We regret that spouses or other guests cannot be accommodated.*

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Important Safety Information for BYETTA® (exenatide) injection

Contraindications

- BYETTA is contraindicated in patients with prior severe hypersensitivity reactions to exenatide or to any of the product components.

Warnings and Precautions

- **Based on postmarketing data BYETTA has been associated with acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. After initiation and dose increases of BYETTA, observe patients carefully for pancreatitis (persistent severe abdominal pain, sometimes radiating to the back, with or without vomiting). If pancreatitis is suspected, BYETTA should be discontinued promptly. BYETTA should not be restarted if pancreatitis is confirmed.**
- Increased risk of hypoglycemia when used in combination with glucose-independent insulin secretagogues (eg, sulfonylureas). Clinicians may consider reducing the sulfonylurea (SFU) dose.
- Postmarketing reports of altered renal function, including increased serum creatinine, renal impairment, worsened chronic renal failure, and acute renal failure, sometimes requiring hemodialysis and kidney transplantation. BYETTA should not be used in patients with severe renal impairment or end-stage renal disease. Use with caution in patients with renal transplantation or when initiating or escalating the dose in patients with moderate renal failure.
- Not recommended in patients with severe gastrointestinal disease (eg, gastroparesis).
- Patients may develop antibodies to exenatide. Formation of high titer antibodies could result in worsening of or failure to achieve adequate glycemic control. If this occurs, consider alternative antidiabetic therapy.
- Postmarketing reports of serious hypersensitivity reactions (eg, anaphylaxis and angioedema). If this occurs, patients should discontinue BYETTA and other suspect medications and promptly seek medical advice.
- No clinical studies establishing conclusive evidence of macrovascular risk reduction with BYETTA or any other antidiabetic drug.

Adverse Reactions

- Most common adverse reactions in registration trials associated with BYETTA vs placebo (PBO): nausea (44% vs 18%), vomiting (13% vs 4%), and diarrhea (13% vs 6%). Other adverse reactions ≥5% and more than PBO: feeling jittery, dizziness, headache, and dyspepsia. With a thiazolidinedione (TZD), adverse reactions were similar; as monotherapy, most common was nausea (8% vs 0%).
- Hypoglycemia incidence, BYETTA vs PBO, with metformin (MET): 5.3% (10 mcg) and 4.5% (5 mcg) vs 5.3%; with SFU, 35.7% (10 mcg) and 14.4% (5 mcg) vs 3.3%; with MET + SFU, 27.8% (10 mcg) and 19.2% (5 mcg) vs 12.6%; with TZD, 10.7% (10 mcg) vs 7.1%; as monotherapy, 3.8% (10 mcg) and 5.2% (5 mcg) vs 1.3%.
- Withdrawals: as monotherapy, 2 of 155 BYETTA patients withdrew due to headache and nausea vs 0 PBO; with MET and/or SFU vs PBO, nausea (3% vs <1%) and vomiting (1% vs 0); with TZD ± MET, nausea (9%) and vomiting (5%), with <1% of PBO patients withdrawing due to nausea.

Continued on next page

Drug Interactions

- BYETTA slows gastric emptying and can reduce the extent and rate of absorption of orally administered drugs. Use with caution with medications that have a narrow therapeutic index or require rapid gastrointestinal absorption. Medications dependent on threshold concentrations for efficacy should be taken at least 1 hour before BYETTA.
- Postmarketing reports of increased international normalized ratio (INR) sometimes associated with bleeding with concomitant use of warfarin. Monitor INR frequently until stable upon initiation or alteration of BYETTA.

Use in Specific Populations

- Based on animal data, BYETTA may cause fetal harm and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Caution should be exercised when administered to a nursing woman.
- Safety and effectiveness have not been established in pediatric patients.

For complete safety profile and other important prescribing considerations, see the accompanying Prescribing Information and Medication Guide.