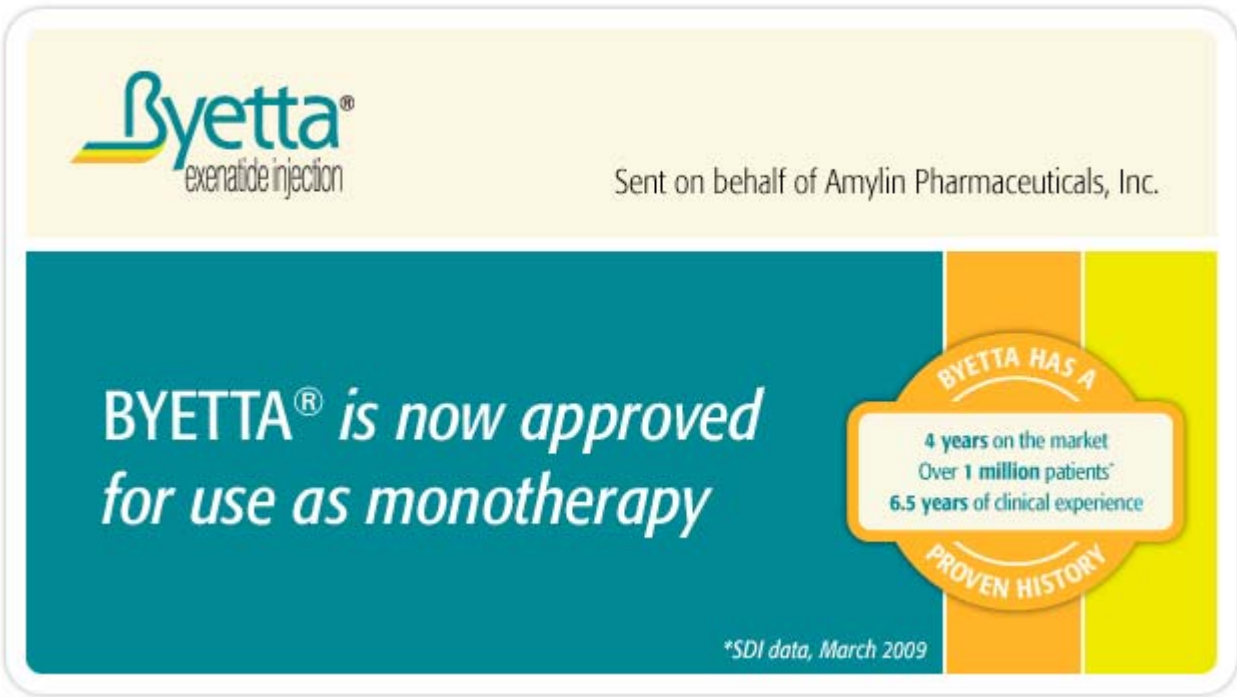

Indication

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

Important Limitations of Use for BYETTA

- BYETTA is not a substitute for insulin. BYETTA should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.
- The concurrent use of BYETTA with insulin has not been studied and cannot be recommended.
- BYETTA has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.

Important Safety Information for BYETTA

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. If pancreatitis is suspected, BYETTA should be discontinued promptly. BYETTA should not be restarted if pancreatitis is confirmed.**
- The risk of hypoglycemia is increased when BYETTA is used in combination with a sulfonylurea. Clinicians may consider reducing the sulfonylurea dose.
- There have been postmarketing reports of renal impairment sometimes requiring hemodialysis and kidney transplantation. BYETTA should not be used in patients with severe renal impairment or end-stage renal disease and should be used with caution in patients with renal transplantation. Caution should be applied when initiating BYETTA or escalating the dose of BYETTA in patients with moderate renal failure.
- Use of BYETTA is not recommended in patients with severe gastrointestinal disease (e.g., gastroparesis).
- There have been postmarketing reports of hypersensitivity reactions (e.g., anaphylaxis and angioedema). If hypersensitivity reaction occurs, the patient should discontinue BYETTA and other suspect medications and promptly seek medical advice.

Adverse Reactions

- The most common (≥5%) adverse reactions occurring more frequently than placebo in clinical trials were nausea, hypoglycemia, vomiting, diarrhea, feeling jittery, dizziness, headache, and dyspepsia. Nausea usually decreases over time.

Drug Interactions

- There have been postmarketing reports of increased international normalized ratio (INR) sometimes associated with bleeding with concomitant use of warfarin and BYETTA. Monitor INR frequently until stable upon initiation or alteration of BYETTA therapy.

Use in Specific Populations

- Based on animal data, BYETTA may cause fetal harm. BYETTA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Caution should be exercised when BYETTA is administered to a nursing woman.

For complete safety profile and other important prescribing considerations, click the links for Prescribing Information and Medication Guide.