

NOVEX® (novexumab)

Full Prescribing Information

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use NOVEX safely and effectively. See full prescribing information for NOVEX.

1. INDICATIONS AND USAGE

NOVEX is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use: NOVEX is not recommended as first-line therapy for patients inadequately controlled on diet and exercise. NOVEX has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis. NOVEX is not indicated for use in patients with type 1 diabetes mellitus.

2. DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage

- Starting dose: 0.25 mg subcutaneously once weekly for 4 weeks. The 0.25 mg dose is intended for treatment initiation and is not effective for glycemic control.
- After 4 weeks on the 0.25 mg dose, increase to 0.5 mg once weekly.
- If additional glycemic control is needed after at least 4 weeks on the 0.5 mg dose, increase to 1 mg, then 1.5 mg, and finally 2 mg once weekly.
- Maximum recommended dose: 2 mg once weekly.

2.2 Administration Instructions

- Inject subcutaneously in the abdomen, thigh, or upper arm region.
- Administer once weekly, on the same day each week, at any time of day, with or without meals.
- The day of weekly administration can be changed if necessary as long as the time between two doses is at least 3 days (72 hours).

- If a dose is missed, administer as soon as possible within 5 days after the missed dose. If more than 5 days have passed, skip the missed dose and administer the next dose on the regularly scheduled day.

4. CONTRAINDICATIONS

NOVEX is contraindicated in patients with:

- Personal or family history of medullary thyroid carcinoma (MTC)
- Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
- Known serious hypersensitivity to novexumab or any of the excipients in NOVEX

5. WARNINGS AND PRECAUTIONS

5.1 Risk of Thyroid C-Cell Tumors

In rodents, novexumab causes thyroid C-cell tumors. It is unknown whether NOVEX causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans. NOVEX is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2. Counsel patients regarding the potential risk of MTC and symptoms of thyroid tumors.

5.2 Pancreatitis

Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with GLP-1 receptor agonists. Observe patients carefully for signs and symptoms of pancreatitis. If pancreatitis is suspected, discontinue NOVEX promptly.

6. ADVERSE REACTIONS

The most common adverse reactions ($\geq 5\%$ incidence) are: nausea, diarrhea, vomiting, constipation, abdominal pain, headache, fatigue, dyspepsia, dizziness, and abdominal distension.

16. HOW SUPPLIED/STORAGE AND HANDLING

16.2 Storage and Handling

Prior to first use: Store NOVEX in a refrigerator at 36°F to 46°F (2°C to 8°C). Do not freeze. Do not use NOVEX if it has been frozen.

After first use: Store at room temperature below 86°F (30°C) or in a refrigerator at 36°F to 46°F (2°C to 8°C). Discard the pen 56 days after first use.

This is a fictional medication for demonstration purposes only.