

HIGHLIGHTS OF PRESCRIBING INFORMATION

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

Tyzeka (telbivudine) tablets

Initial U.S. Approval: 2006

WARNING: LACTIC ACIDOSIS, SEVERE HEPATOMEGALY WITH STEATOSIS & SEVERE ACUTE EXACERBATIONS of HEPATITIS B

See full prescribing information for complete boxed warning.

- Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues (5.1).
- Severe acute exacerbations of hepatitis B have been reported in patients who discontinued anti-hepatitis B therapy, including Tyzeka. Hepatic function should be monitored closely in patients who discontinue therapy. Resumption of anti-hepatitis B therapy may be warranted (5.2).

RECENT MAJOR CHANGES

- Warnings and Precautions, Peripheral Neuropathy (5.4) 1/2009

INDICATIONS AND USAGE

Tyzeka is an HBV nucleoside analogue reverse transcriptase inhibitor indicated for the treatment of chronic hepatitis B in adult patients with evidence of viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease (1.1).

DOSAGE AND ADMINISTRATION

- Adults and Adolescents (≥ 16 years of age): 600 mg once daily, taken orally, with or without food (2.1).
- Renal Impairment: Dose adjustment required in patients with creatinine clearance < 50 mL/min (2.2); as follows:

| Creatinine Clearance (mL/min) | Telbivudine Dose Tablet (600 mg) |
|---|-------------------------------------|
| ≥ 50 | 1 tab every 24 hrs |
| 30 – 49 | 1 tab every 48 hrs |
| < 30 (not requiring dialysis) | 1 tab every 72 hrs |
| End stage renal disease (ESRD) ¹ | 1 tab every 96 hrs |

¹ When administered on hemodialysis days, administer Tyzeka after hemodialysis (2.2)

DOSAGE FORMS AND STRENGTHS

- Tablet: 600-mg tablets supplied in 30-count bottles (3.1).

CONTRAINDICATIONS

None (4).

WARNINGS AND PRECAUTIONS

- Lactic acidosis and severe hepatomegaly with steatosis: If suspected, treatment should be suspended (5.1).
- Severe acute exacerbations of hepatitis B after discontinuation: Monitor hepatic function closely for at least several months (5.2, 6.1).
- Myopathy: TYZEKA should be interrupted if myopathy suspected; and discontinued if confirmed. It is unknown whether risk of myopathy is increased with concomitant use of other medications associated with myopathy (5.3).
- Peripheral Neuropathy: TYZEKA should be interrupted if peripheral neuropathy is suspected; and discontinued if confirmed. Risk increased when used in combination with pegylated interferon alfa-2a. Avoid concomitant use of pegylated interferon alfa-2a or other interferons (5.4, 7).

ADVERSE REACTIONS

In clinical trials, the most common adverse reactions ($\geq 3\%$), of any severity, were: fatigue, increased creatine kinase (CK), headache, cough, diarrhea, abdominal pain, nausea, pharyngolaryngeal pain, arthralgia, pyrexia, rash, back pain, dizziness, myalgia, ALT increased, dyspepsia, insomnia, and abdominal distension (6.1). The most common adverse events resulting in Tyzeka discontinuation included increased CK, nausea, diarrhea, fatigue, myalgia, and myopathy (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Novartis Pharmaceuticals Corporation at 1-888-669-6682 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

DRUG INTERACTIONS

- Co-administration of Tyzeka with drugs that affect renal function may alter plasma concentrations of telbivudine and/or coadministered drug (7).
- Co-administration of Tyzeka with pegylated interferon alfa-2a or other interferons may increase the risk and severity of peripheral neuropathy (7).

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide

Revised 1/2009

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