telbivudine

Classification
Therapeutic: antivirals
Pharmacologic: nucleoside analogues

Pregnancy Category B

Indications
Management of chronic hepatitis B with evidence of currently active disease.

Action
Converted intracellularly to the triphosphate active metabolite which inhibits DNA polymerase by acting as a nucleoside analogue. Result is inhibition of viral replication.

Therapeutic Effects:
Decreased progression of chronic hepatitis B infection.

Pharmacokinetics
Absorption: Rapidly absorbed following oral administration; bioavailability unknown.
Distribution: Widely distributed into tissues.
Metabolism and Excretion: Excreted entirely as unchanged drug; no metabolism.
Half-life: Effective—15 hr; elimination half-life—40–49 hr.

TIME/ACTION PROFILE (blood levels)
ROUTE ONSET PEAK DURATION*
PO unknown 1–4 hr 24 hr

*Patients with normal renal function.

Contraindications/Precautions
Contraindicated in: Hypersensitivity; Concurrent use of pegylated interferon alfa-2a; Lactation: Lactation.
Use Cautiously in: Moderate to severe renal impairment (dosage modification recommended for CCr <50 mL/min); Discontinuation of medication (may result in exacerbation of hepatitis B); Geri: Consider age-related ↓ in renal function; OB: Use only if maternal benefit outweighs fetal risk; Pedi: Children ≤16 yr (safety not established).

Adverse Reactions/Side Effects
CV: fatigue, headache.
GI: hepatomegaly.
Hemat: neutropenia.
Metabolic: lactic acidosis.
Musculoskeletal: myopathy.
Neuro: peripheral neuropathy.
Misc: fever.

Interactions
Drug-Drug: ↑ risk of peripheral neuropathy when used with pegylated interferon alfa-2a; concomitant use contraindicated. Drugs that alter renal function may alter blood levels and effectiveness.

Route/Dosage
PO (Adults and Children ≥16 yr): 600 mg daily.

Renal Impairment
PO (Adults and Children ≥16 yr): CCr 30–49 mL/min—600 mg every 48 hr; CCr ≤30 mL/min (not on dialysis)—600 mg every 72 hr; End stage renal disease—600 mg every 96 hr.

NURSING IMPLICATIONS
Assessment
● Monitor signs of hepatitis (jaundice, fatigue, anorexia, pruritus) during therapy.
● Assess for signs of myopathy (diffuse myalgias, muscle tenderness or muscle weakness with increases in creatinine kinase). Interrupt therapy if myopathy is suspected and discontinue therapy if myopathy is diagnosed.
● Lab Test Considerations: Monitor liver function tests during and for at least several months following discontinuation of therapy. May cause ↑ serum CPK, ALT, AST, lipase, amylase, and total bilirubin.
● May cause neutropenia and thrombocytopenia.
● Monitor HBV-DNA every 6 mo to determine response to therapy.

Potential Nursing Diagnoses
Risk for infection (Indications)

Implementation
● PO: Administer without regard to food.

Patient/Family Teaching
● Instruct patient to take telbivudine as directed and not to discontinue therapy without consulting health care professional. Severe acute exacerbations of hepatitis B have occurred following discontinuation of therapy.

OHT: Other Healthcare Team member
OPT: Other Provider
- = Generic Implication
- = Significant Implication
AUX: Auxiliary
IND: Indicated
CPT: Commonly Related Procedure
NRT: Non-Related Treatment
- = Occasional Use
- = Required Use
- = Discontinued
- = Not Required
Have occurred when therapy was discontinued. Take missed doses as soon as re-
membered unless almost time for next dose, do not double doses. Advise patients
to read the patient package insert prior to therapy and with each prescription re-
fill.

- Advise patients to notify health care professionals promptly if signs of lactic acido-
sis (weakness or tiredness, unusual muscle pain, troubled breathing, nausea and vomiting, feeling cold, especially in arms or legs, dizziness, fast or irregular heart beat), hepatotoxicity (yellow skin or eyes, dark urine, light-colored stools, lack of appetite, nausea, lower stomach pain) or myopathy (unexplained muscle aches, pain, tenderness or weakness) occur or if these symp-
toms worsen.

- Inform patient that telbivudine does not cure hepatitis B. Telbivudine does not re-
duce the risk of transmission of hepatitis B to others through sexual contact or
blood contamination. Caution patients to use a condom during sexual contact and
avoid sharing needles or donating blood to prevent spreading hepatitis B to oth-
ers. Advise patients that the long-term effects of telbivudine are unknown.

- Encourage pregnant female patients to register in the Antiretroviral Pregnancy
Registry at 1-800-258-4263 to monitor fetal outcomes. Advise patients not to
breast feed during therapy.

Evaluation/Desired Outcomes

- Decreased progression of chronic hepatitis B infection. For patients with incom-
plete viral suppression (HBV DNA >300 copies/mL) after 24 wk of treatment, al-
ternate therapy should be instituted. HBV DNA should be monitored every 6 mo to
assure continued response. If patients test positive for HBV DNA at any time after
fluconazole response, alternate treatment should be continued.

Why was this drug prescribed for your patient?