Telbivudine

- **INDICATIONS AND DOSE**

Chronic hepatitis B infection with compensated liver disease, evidence of viral replication, and histologically documented active liver inflammation or fibrosis, when other treatment is not appropriate

- BY MOUTH
- Adult: 600 mg once daily

- **CAUTIONS** Lamivudine-resistant chronic hepatitis B—risk of telbivudine resistance

  CAUTIONS, FURTHER INFORMATION Discontinue if deterioration in liver function, hepatic steatosis, progressive hepatomegaly or unexplained lactic acidosis.
- **INTERACTIONS** → Appendix 1: telbivudine
- **SIDE-EFFECTS**
- **Common or very common** Abdominal pain · cough · diarrhoea · dizziness · fatigue · headache · nausea · rash
- **Uncommon** Arthralgia · malaise · muscle complaints · nerve disorders · pain · sensation abnormal · taste altered
- **Rare or very rare** Lactic acidosis
- **PREGNANCY** Manufacturer advises use only if potential benefit outweighs risk.
- **BREAST FEEDING** Manufacturer advises avoid—present in milk in *animal* studies.
- **RENAL IMPAIRMENT**

  Dose adjustments 600 mg every 48 hours if eGFR 30–49 mL/minute/1.73 m^2; 600 mg every 72 hours if eGFR less than 30 mL/minute/1.73 m^2.
- **MONITORING REQUIREMENTS** Monitor liver function tests every 3 months and viral markers of hepatitis B every 3–6 months during treatment (continue monitoring for at least 1 year after discontinuation—recurrent hepatitis may occur on discontinuation.
- **PATIENT AND CARER ADVICE**

  Muscle effects and peripheral neuropathy Patients should be advised to promptly report unexplained muscle pain, tenderness, or weakness, or numbness, tingling or burning sensations.
- **NATIONAL FUNDING/ACCESS DECISIONS**

NICE decisions

- **Telbivudine for chronic hepatitis B (August 2008)** NICE TA154

  Telbivudine is not recommended for the treatment of chronic hepatitis B. Patients currently receiving telbivudine can continue treatment until they and their clinician consider it appropriate to stop.

  www.nice.org.uk/TA154

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.

Tablet

- **Sebivo** (Novartis Pharmaceuticals UK Ltd)

  Telbivudine 600 mg Sebivo 600mg tablets | 28 tablet PoM £290.33

ANTIVIRALS › NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS

F 683

Tenofovir alafenamide

26-Feb-2018

- **INDICATIONS AND DOSE**

Chronic hepatitis B (initiated by a specialist)

- BY MOUTH
- Adult: 25 mg once daily (for duration of treatment consult product literature)

- **CAUTIONS** Decompensated liver disease · HIV co-infection
- **INTERACTIONS** → Appendix 1: tenofovir alafenamide
- **SIDE-EFFECTS**
- **Common or very common** Abdominal distension · arthralgia · flatulence
- **Frequency not known** Hepatitis aggravated (during or following treatment) · nephrotoxicity
- **BREAST FEEDING** Manufacturer advises avoid—present in milk in *animal* studies.
- **HEPATIC IMPAIRMENT** Manufacturer advises caution in decompensated hepatic disease (no information available).
- **PRE-TREATMENT SCREENING** Manufacturer advises HIV antibody testing should be offered to those with unknown HIV-1 status before initiation of treatment.
- **MONITORING REQUIREMENTS** Manufacturer advises monitor liver function tests at repeated intervals during treatment and for at least 6 months after last dose—recurrent hepatitis may occur on discontinuation.
- **PATIENT AND CARER ADVICE**

  Missed doses Manufacturer advises if a dose is more than 18 hours late, the missed dose should not be taken and the next dose should be taken at the normal time.

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.

Tablet

CAUTIONARY AND ADVISORY LABELS 21

- **Vemlidy** (Gilead Sciences International Ltd) ▼

  Tenofovir alafenamide (as Tenofovir alafenamide fumarate) 25 mg Vemlidy 25mg tablets | 30 tablet PoM £325.73

ANTIVIRALS › NUCLEOTIDE ANALOGUES

Adefovir dipivoxil

- **INDICATIONS AND DOSE**

Chronic hepatitis B infection with either compensated liver disease with evidence of viral replication, and histologically documented active liver inflammation and fibrosis, when other treatment not appropriate or decompensated liver disease in combination with another antiviral for chronic hepatitis B that has no cross-resistance to adefovir

- BY MOUTH
- Adult: 10 mg once daily

- **CAUTIONS** Elderly

  CAUTIONS, FURTHER INFORMATION Discontinue if deterioration in liver function, hepatic steatosis, progressive hepatomegaly or unexplained lactic acidosis.
- **INTERACTIONS** → Appendix 1: adefovir
- **SIDE-EFFECTS**
- **Common or very common** Asthenia · diarrhoea · flatulence · gastrointestinal discomfort · headache · nausea · renal impairment · skin reactions · vomiting
- **Frequency not known** Bone fracture · bone pain · hypophosphataemia · myopathy · nephrotoxicity · osteomalacia · pancreatitis · proximal renal tubulopathy
- **CONCEPTION AND CONTRACEPTION** Effective contraception required during treatment.
- **PREGNANCY** Toxicity in *animal* studies—manufacturer advises use only if potential benefit outweighs risk.
- **BREAST FEEDING** Manufacturer advises avoid—no information available.
- **RENAL IMPAIRMENT** No information available if eGFR less than 10 mL/minute/1.73 m^2.

  Dose adjustments 10 mg every 48 hours if eGFR 30–50 mL/minute/1.73 m^2; 10 mg every 72 hours if eGFR 10–30 mL/minute/1.73 m^2.

  Monitoring Monitor renal function more frequently in patients with renal impairment.