

### NATIONAL FUNDING/ACCESS DECISIONS

#### NICE decisions

- ▶ **Tenofovir disoproxil for the treatment of chronic hepatitis B (July 2009)** NICE TA173

Tenofovir is an option for the treatment of chronic hepatitis B.

[www.nice.org.uk/guidance/ta173](http://www.nice.org.uk/guidance/ta173)

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

#### Granules

CAUTIONARY AND ADVISORY LABELS 21

- ▶ **Viread** (Gilead Sciences International Ltd)

**Tenofovir disoproxil (as Tenofovir disoproxil fumarate)** 33 mg per 1 gram Viread 33mg/g granules | 60 gram [PoM](#) £54.50

#### Tablet

CAUTIONARY AND ADVISORY LABELS 21

- ▶ **Tenofovir disoproxil (Non-proprietary)**

**Tenofovir disoproxil 245 mg** Tenofovir 245mg tablets | 30 tablet [PoM](#) £64.08 DT = £39.05 (Hospital only) | 30 tablet [PoM](#) £16.84-£204.39 DT = £39.05 | 168 tablet [PoM](#) £36.36

- ▶ **Viread** (Gilead Sciences International Ltd)

**Tenofovir disoproxil (as Tenofovir disoproxil fumarate)**

**123 mg** Viread 123mg tablets | 30 tablet [PoM](#) £102.60 DT = £102.60

**Tenofovir disoproxil (as Tenofovir disoproxil fumarate)**

**163 mg** Viread 163mg tablets | 30 tablet [PoM](#) £135.98 DT = £135.98

**Tenofovir disoproxil (as Tenofovir disoproxil fumarate)**

**204 mg** Viread 204mg tablets | 30 tablet [PoM](#) £170.19 DT = £170.19

**Tenofovir disoproxil 245 mg** Viread 245mg tablets |

30 tablet [PoM](#) £204.39 DT = £39.05

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## Zidovudine

(Azidothymidine; AZT)

### INDICATIONS AND DOSE

**HIV infection in combination with other antiretroviral drugs**

- ▶ BY MOUTH

▶ Adult: 250–300 mg twice daily

**Prevention of maternal-fetal HIV transmission**

- ▶ BY MOUTH, OR BY INTRAVENOUS INFUSION

▶ Adult: Seek specialist advice (combination therapy preferred) (consult local protocol)

**HIV infection in combination with other antiretroviral drugs in patients temporarily unable to take zidovudine by mouth**

- ▶ BY INTRAVENOUS INFUSION

▶ Adult: 0.8–1 mg/kg every 4 hours usually for not more than 2 weeks, dose approximating to 1.2–1.5 mg/kg every 4 hours by mouth

- **CONTRA-INDICATIONS** Abnormally low haemoglobin concentration (consult product literature) · abnormally low neutrophil counts (consult product literature)

- **CAUTIONS** Elderly · lactic acidosis · risk of haematological toxicity particularly with high dose and advanced disease · vitamin B<sub>12</sub> deficiency (increased risk of neutropenia)

#### CAUTIONS, FURTHER INFORMATION

- ▶ **Lactic acidosis** Lactic acidosis associated with hepatomegaly and hepatic steatosis has been reported with zidovudine. Use with caution in patients with hepatomegaly, hepatitis, or other risk factors for liver disease and hepatic steatosis (including obesity and alcohol abuse). Discontinue treatment if symptoms of hyperlactataemia, lactic acidosis, progressive hepatomegaly or rapid deterioration of liver function become apparent.

- **INTERACTIONS** → Appendix 1: zidovudine

- **SIDE-EFFECTS**

#### GENERAL SIDE-EFFECTS

- ▶ **Common or very common** Leucopenia · malaise · myalgia

- ▶ **Uncommon** Bone marrow disorders · dyspnoea · fever · flatulence · generalised pain · myopathy · thrombocytopenia

- ▶ **Rare or very rare** Alertness decreased · anxiety · appetite decreased · cardiomyopathy · chest pain · chills · cough · depression · drowsiness · dyspepsia · gynaecomastia · hepatic disorders · hyperhidrosis · influenza like illness · nail discolouration · oral discolouration · paraesthesia · pure red cell aplasia · seizure · taste altered · urinary frequency increased

- ▶ **Frequency not known** Lipotrophy

#### SPECIFIC SIDE-EFFECTS

- ▶ With intravenous use Weight increased

#### SIDE-EFFECTS, FURTHER INFORMATION Anaemia and myelosuppression

If anaemia or myelosuppression occur, reduce dose or interrupt treatment according to product literature, or consider other treatment.

**Lipodystrophy syndrome** Metabolic effects may occur with zidovudine; plasma lipids and blood glucose concentrations should be measured routinely.

- **HEPATIC IMPAIRMENT** Manufacturer advises caution in moderate to severe impairment (increased risk of accumulation).

**Dose adjustments** Manufacturer advises consider dose reduction in moderate to severe impairment—consult product literature.

- **RENAL IMPAIRMENT**

**Dose adjustments** Reduce oral dose to 300–400 mg daily in divided doses or intravenous dose to 1 mg/kg 3–4 times daily if eGFR is less than 10 mL/minute/1.73 m<sup>2</sup>.

- **MONITORING REQUIREMENTS** Monitor full blood count after 4 weeks of treatment, then every 3 months.

- **DIRECTIONS FOR ADMINISTRATION**

- ▶ With intravenous use For *intermittent intravenous infusion*, dilute to a concentration of 2 mg/mL or 4 mg/mL with Glucose 5% and give over 1 hour.

- **PRESCRIBING AND DISPENSING INFORMATION** The abbreviation AZT which is sometimes used for zidovudine has also been used for another drug.

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

#### Solution for infusion

- ▶ **Retrovir** (ViiV Healthcare UK Ltd)

**Zidovudine 10 mg per 1 ml** Retrovir IV 200mg/20ml concentrate for solution for infusion vials | 5 vial [PoM](#) £52.48

#### Oral solution

- ▶ **Retrovir** (ViiV Healthcare UK Ltd)

**Zidovudine 10 mg per 1 ml** Retrovir 100mg/10ml oral solution sugar-free | 200 ml [PoM](#) £20.91

#### Capsule

- ▶ **Zidovudine (Non-proprietary)**

**Zidovudine 100 mg** Zidovudine 100mg capsules | 60 capsule [PoM](#) £53.31

**Zidovudine 250 mg** Zidovudine 250mg capsules | 60 capsule [PoM](#) £13.32

- ▶ **Retrovir** (ViiV Healthcare UK Ltd)

**Zidovudine 100 mg** Retrovir 100mg capsules | 100 capsule [PoM](#) £104.54

**Zidovudine 250 mg** Retrovir 250mg capsules | 40 capsule [PoM](#) £104.54