

- **UNLICENSED USE** *Trizivir*® not licensed for use in children.
- **INTERACTIONS** → Appendix 1: abacavir · lamivudine · zidovudine
- **RENAL IMPAIRMENT** Avoid *Trizivir*® if estimated glomerular filtration rate less than 50 mL/minute/1.73 m².

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

Tablet

- ▶ *Trizivir* (ViiV Healthcare UK Ltd)
Lamivudine 150 mg, Abacavir (as Abacavir sulfate) 300 mg, Zidovudine 300 mg *Trizivir* tablets | 60 tablet [PoM](#) E509.06

F 431

Didanosine

01-Sep-2016

(ddi; DDI)

● **INDICATIONS AND DOSE****HIV infection in combination with other antiretroviral drugs**

▶ BY MOUTH

- ▶ Child 1-7 months: 50–100 mg/m² twice daily
- ▶ Child 8 months-17 years: 180–240 mg/m² once daily; usual dose 200 mg/m² once daily; maximum 400 mg per day

- **UNLICENSED USE** Tablets not licensed for use in children under 3 months. EC capsules not licensed for use in children under 6 years.

- **CAUTIONS** History of pancreatitis (preferably avoid, otherwise extreme caution) · hyperuricaemia · lactic acidosis · peripheral neuropathy

CAUTIONS, FURTHER INFORMATION

- ▶ **Lactic acidosis** Lactic acidosis associated with hepatomegaly and hepatic steatosis has been reported with didanosine. 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: didanosine

● **SIDE-EFFECTS**

- ▶ **Common or very common** Arthralgia · chills · dry mouth · fever · flatulence · gynaecomastia · hepatic disorders · pain · peripheral neuropathy (switch to another antiretroviral if peripheral neuropathy develops)
- ▶ **Uncommon** Acute kidney injury · alopecia · diabetes mellitus · dry eye · haemodialysis · hyperglycaemia · hypoglycaemia · leucopenia · myopathy · optic neuritis · retinal discolouration · sialadenitis
- ▶ **Rare or very rare** Parotid gland enlargement
- ▶ **Frequency not known** Lipotrophy

SIDE-EFFECTS, FURTHER INFORMATION **Pancreatitis**

Suspend treatment if serum lipase raised or if symptoms of pancreatitis develop; discontinue if pancreatitis confirmed. Whenever possible avoid concomitant treatment with other drugs known to cause pancreatic toxicity; monitor closely if concomitant therapy unavoidable. Since significant elevations of triglycerides cause pancreatitis monitor closely if elevated.

Lipodystrophy syndrome Metabolic effects may occur with didanosine: these include fat redistribution, insulin resistance, and dyslipidaemia—collectively termed lipodystrophy syndrome. Manufacturer advises monitoring of plasma lipids and blood-glucose.

- **PREGNANCY** Manufacturer advises use only if potential benefit outweighs risk.

● **HEPATIC IMPAIRMENT**

Monitoring In hepatic impairment, monitor for toxicity.

● **RENAL IMPAIRMENT**

Dose adjustments Reduce dose if estimated glomerular filtration rate less than 60 mL/minute/1.73 m²; consult product literature.

- **MONITORING REQUIREMENTS** Ophthalmological examination (including visual acuity, colour vision, and dilated fundus examination) recommended annually or if visual changes occur.

- **DIRECTIONS FOR ADMINISTRATION** Capsules should be swallowed whole and taken at least 2 hours before or 2 hours after food.

- **PATIENT AND CARER ADVICE** Patients or carers should be given advice on how to administer didanosine capsules.

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

Gastro-resistant capsule

CAUTIONARY AND ADVISORY LABELS 25

- ▶ *Videx EC* (Bristol-Myers Squibb Pharmaceuticals Ltd)

Didanosine 125 mg *Videx EC* 125mg capsules | 30 capsule [PoM](#)

£48.18 (Hospital only)

Didanosine 250 mg *Videx EC* 250mg capsules | 30 capsule [PoM](#)

£96.37 (Hospital only)

Didanosine 400 mg *Videx EC* 400mg capsules | 30 capsule [PoM](#)

£154.19 (Hospital only)

Elvitegravir with cobicistat, emtricitabine and tenofovir alafenamide

22-May-2019

The properties listed below are those particular to the combination only. For the properties of the components please consider, emtricitabine p. 434, elvitegravir, cobicistat, tenofovir alafenamide p. 415.

● **INDICATIONS AND DOSE****HIV-1 infection (specialist use only)**

▶ BY MOUTH

- ▶ Child 6–11 years (body-weight 25 kg and above): 1 tablet once daily
- ▶ Child 12–17 years (body-weight 35 kg and above): 1 tablet once daily

IMPORTANT SAFETY INFORMATION

MHRA/CHM ADVICE: ELVITEGRAVIR BOOSTED WITH COBICISTAT: AVOID USE IN PREGNANCY DUE TO RISK OF TREATMENT FAILURE AND MATERNAL-TO-CHILD TRANSMISSION OF HIV-1 (APRIL 2019)

Pharmacokinetic data show mean exposure of elvitegravir boosted with cobicistat (available in combination in *Genvoya*® and *Stribild*®) to be lower during the second and third trimesters of pregnancy than postpartum. Low elvitegravir exposure may be associated with an increased risk of treatment failure and an increased risk of HIV-1 transmission to the unborn child. For further information, see *Pregnancy*.

- **INTERACTIONS** → Appendix 1: cobicistat · elvitegravir · tenofovir alafenamide

● **SIDE-EFFECTS**

- ▶ **Common or very common** Abnormal dreams · diarrhoea · dizziness · fatigue · flatulence · gastrointestinal discomfort · headache · nausea · skin reactions · vomiting
- ▶ **Uncommon** Anaemia · angioedema · depression
- ▶ **Frequency not known** Nephrotoxicity · osteonecrosis · weight increased

- **CONCEPTION AND CONTRACEPTION** Manufacturer advises effective contraception in women of childbearing potential; if using a hormonal contraceptive, it must