

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan All Wales Medicines Strategy Group



Final Appraisal Recommendation

Advice Number: 2313 – July 2013

Tenofovir disoproxil (as fumarate) (Viread®) 245 mg film coated tablets and 33 mg/g granules

Limited submission by Gilead Sciences Ltd

Recommendation of the All Wales Medicines Strategy Group

Tenofovir disoproxil (as fumarate) (Viread®) 245 mg film-coated tablets are recommended for use within NHS Wales for the treatment of chronic hepatitis B in adolescents 12 to < 18 years of age with compensated liver disease and evidence of immune active disease, i.e. active viral replication, persistently elevated serum ALT levels and histological evidence of active inflammation and/or fibrosis.

Tenofovir disoproxil (as fumarate) (Viread®) 33 mg/g granules are recommended for use within NHS Wales for the treatment of chronic hepatitis B in adolescents 12 to < 18 years of age for whom a solid dosage form is not appropriate with: compensated liver disease and evidence of immune active disease, i.e. active viral replication, persistently elevated serum ALT levels and histological evidence of active inflammation and/or fibrosis.

Additional note(s):

- Please refer to the Summary of Product Characteristics for the full licensed indication.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 1880), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

The All Wales Therapeutics and Toxicology Centre (AWTTC) reviewed this appraisal recommendation in December 2023. No new evidence was

identified that is likely to significantly affect the current recommendation. Therefore, this recommendation has been transferred to AWMSG's static list of medicine recommendations.

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