This brochure provides important advice on the management of potential renal and bone effects of emtricitabine, tenofovir combination in HIV-1 infected adolescents aged 12 to <18 years, and on the dosing recommendations for emtricitabine tenofovir combination in this population.

Important points to consider

- A multidisciplinary approach is recommended for the management of adolescents with HIV.
- That there is an increased risk of renal disease in HIV infected patients associated with tenofovir disoproxil fumarate-containing products
- Emtricitabine/Tenofovir disoproxil is not recommended for use in paediatric patients with renal impairment
- Avoid concurrent or recent use of nephrotoxic medicinal products. If Emtricitabine/ Tenofovir disoproxil is used with nephrotoxic medicinal products, renal function should be closely monitored according to the recommended schedule
- Paediatric patients should have their baseline renal function assessed prior to initiating Emtricitabine/Tenofovir disoproxil therapy
- The importance of regular monitoring of renal function during Emtricitabine/Tenofovir disoproxil therapy
- Recommended schedule for monitoring renal function considering the presence or absence of additional risk factors for renal impairment
- That if serum phosphate is confirmed to be < 3.0 mg/dL (0.96 mmol/L) in any paediatric patient receiving tenofovir disoproxil fumarate, renal function should be re-evaluated within one week. If renal abnormalities are detected or suspected then consultation with a nephrologist should be obtained to consider interruption of Emtricitabine/Tenofovir disoproxil treatment.
- That Emtricitabine/Tenofovir disoproxil may cause a reduction in BMD and the effects of Emtricitabine/Tenofovir disoproxil associated changes in BMD on longterm bone health and future fracture risk are currently unknown in paediatric patients
- If bone abnormalities are suspected or detected, consult with an endocrinologist and/or a nephrologist.

Management of renal effects

There are uncertainties associated with the long term effects of tenofovir disoproxil fumarate renal toxicity. Moreover, the reversibility of renal toxicity cannot be fully ascertained.
Therefore, a multidisciplinary approach is recommended to adequately weigh on a case by case basis the benefit/risk balance of treatment, decide the appropriate monitoring during treatment (including decision for treatment withdrawal) and consider the need for supplementation.
If serum phosphate is confirmed to be < 3.0 mg/dl (0.96 mmol/l) in any paediatric patient receiving Emtricitabine/Tenofovir disoproxil fumarate, renal function should be re-evaluated within one week, including measurements of blood glucose, blood potassium and urine glucose concentrations. If renal abnormalities are suspected or detected then consultation with a nephrologist should be obtained to consider interruption of treatment. Interrupting treatment with emtricitabine/ tenofovir should also be considered in case of progressive decline of renal function when no other cause has been identified.

Management of bone effects

Tenofovir disoproxil fumarate (TDF) may cause a reduction in BMD.

Reductions in BMD have been reported in paediatric patients. In adolescents, the BMD Zscores at 48 weeks observed in subjects who received TDF were lower than those observed in subjects who received placebo. In children, the BMD Z-scores observed at 48 weeks in subjects who switched to TDF were lower than those observed in subjects who remained on their stavudine or zidovudine containing regimen. The effects of TDF associated changes in BMD on long term bone health and future fracture risk are currently unknown. If bone abnormalities are suspected or detected, then consultation with an endocrinologist and/or anephrologist should be obtained.

Dosing recommendations for TDF in Adolescents

Treatment of HIV in adults and adolescents aged 12 years and older, weighing at least 35 kg:
One tablet, once daily.[1]
Paediatrics with renal impairment:
Use of Emtricitabine/Tenofovir disoproxil fumarate is not recommended in HIV-1 infected paediatric patients under the age of 18 years with renal impairment.[1]

1) Summary of product characteristics Emtricitabine/Tenofovir disoproxil film-coated tablets 200/245 mg.

Please report any adverse events suspected to be caused by the use of Emtricitabine/ Tenofovir disoproxil fumarate to

Medical Information at Accord Healthcare Ltd. via E-mail: medinfo@accord-healthcare.com;
Tel: +44 (0) 1271 385 257; or by completing the online form at
www.accord-healthcare.ie/drug-reaction-report.

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HIV renal educational brochure for prescribers of paediatric patients

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