Nierfunctie: emtricitabine 1018

Clcr = creatinineklaring, ESRD = end-stage renal diseas, GFR = glomerulaire filtratie snelheid,

Onderbouwend	Bewijs	Effect	Opmerkingen
SPC Emtriva 17-11-2016.	0	toename emtricitabine-blootstelling na 1-malig 200 mg emtricitabine van 11,8±2,9 µg•h/ml bij normale nierfunctie naar 19,9±1,1 µg•h/ml bij Clcr 50-80 ml/min, 25,0±5,7 µg•h/ml bij Clcr 30-49 ml/min en 34,0±2,1 µg•h/ml bij Clcr < 30 ml/min	Clcr 15-29 ml/min: 200 mg om de 72 uur Clcr < 15 ml/min (hemodialyse nodig): 200 mg om de 96 uur Veiligheid en werkzaamheid van deze doseringsaanpassing is niet klinisch geëvalueerd.

Overig	Opmerkingen
Pozniak A ea. Switching to tenofovir alafenamide, coformulated with elvitegravir, cobicistat, and emtricitabine, in hiv-infected patients with renal impairment: 48-week results from a single-arm, multicenter, open-label phase 3 study JAIDS 2016;71,530-7.	Tenofovir alafenamide (TAF) is a novel tenofovir prodrug with improved renal and bone safety compared with TDFcontaining regimens. We report the 48 week safety and efficacy of a once-daily single tablet regimen of elvitegravir 150 mg (E), cobicistat 150 mg (C), emtricitabine 200 mg (F), and TAF 10 mg (E/C/F/TAF) in HIV-1-infected patients with mild to moderate renal impairment. Patients with significant comorbidities and mild to moderate renal impairment (eGFR = 30–69 mL/min) who switched to E/C/F/TAF had no change in estimated or actual GFR, whereas proteinuria, proximal renal tubular function, and BMD significantly improved over 48 weeks. Of particular note, patients with eGFR < 50 mL/min who currently require dose adjustment for both TDF and FTC had stable eGFR and significant improvements in tubular function through 48 weeks after switching to once-daily E/C/F/TAF without dose adjustment. In these patients with eGFR < 50 mL/min, adverse events were similar in grade and frequency to patients with eGFR ≥ 50 mL/min, indicating no untoward effects from higher FTC exposure. No cases of proximal tubulopathy occurred. E/C/F/TAF was well tolerated and discontinuations for drug-related adverse events were rare. Our data support the safe use of single tablet E/C/F/TAF in HIV-patients with mild and moderate renal impairment without dose adjustment over the first year of use. Longer duration studies are needed to confirm these initial findings.
Post FA ea. Switching to tenofovir alafenamide, coformulated with elvitegravir, cobicistat, and emtricitabine, in HIV-infected adults with renal impairment: 96-week results from a single-arm, multicenter, open-label phase 3 study. JAIDS Publish Ahead of Print DOI: 10.1097/QAI.0000000000001186	Tenofovir disoproxil fumarate (TDF) is associated with renal and bone toxicity. In a single-arm, open-label study of 242 virologically suppressed, HIV-infected participants with creatinine clearance 30-69 mL/min who switched to elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF), participants had stable creatinine clearance, significant and durable improvements in proteinuria, albuminuria, and tubular proteinuria (P < .001), and significant increases in hip and spine bone mineral density through 96 weeks (P < .001). Eighty-eight percent maintained HIV-1 RNA < 50 c/mL at week 96. These longer-term results support the use of E/C/F/TAF in HIV-infected individuals with mild-moderately impaired renal function.

Risicogroep	

Opmerkingen:

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<u>Clcr < 10 ml/min:</u>

- SPC Emtriva 17-11-2016: Bij patiënten met ESRD die hemodialyse nodig hebben, werd ca. 30% van de dosis emtricitabine teruggevonden in het dialysaat tijdens een 3 uur durende dialyseperiode die binnen 1,5 uur na toediening van de dosis emtricitabine was gestart

	Wijziging kinetiek	Actie	Clcr grens	Datum
Beslissing werkgroep	Ja	Ja	30 ml/min	24 januari 2017