

Date of report 22 Jun 2020

Reported case interaction between Cobicistat and Norgestimate

Drugs suspected to be involved in the DDI

Perpetrator	Daily Dose
Cobicistat	150 (mg)
Dose adjustment performed	Administration Route
No	Oral
Start date	End date
Feb. 11, 2019	Ongoing
Victim	Daily Dose
Norgestimate	Unknown
Dose adjustment performed	Administration Route
No	Oral
Start date	End date
Unknown	Ongoing

Complete list of drugs taken by the patient

Antiretroviral treatment Elvitegravir/Cobicistat/Emtricitabine/Tenofovir-AF

Complete list of all comedications taken by the patient, included that involved in the DDI

Ethinylestradiol, Spironolactone

Clinical case description

Gender	Age
Transgender	31
eGFR (mL/min) >60	Liver function impairment No

Description

31-year-old transgender female patient with HIV infection since 2017 who changed treatment to EVG/c/FTC/TAF after neuropsychiatric toxicity with DTG/ABC/3TC, in February 2019. Several months later the patient began using Ethinylestradiol/Norgestimate and spironolactone as hormonal treatment without medical supervision. Despite no evidence of adverse effects , a potential interaction between cobicistat and estradiol/norgestimate is possible. The clinical significance of this increase is unknown but it could increase the risk of deep vein thrombosis, pulmonary embolism, stroke or myocardial infarction.

Clinical Outcome

No unwanted outcome

Editorial Comment

Possible interaction between cobicistat and ethinylestradiol still have very low evidence in clinical practice. Furthermore, coadministration of Genvoya with oral contraceptives containing progestogens and other than norgestimate has not been studied. Coadministration of norgestimate (0.180/0.215 mg once daily), ethinylestradiol (0.025 mg once daily) and elvitegravir/cobicistat (150/150 mg once daily, with emtricitabine and tenofovir-DF) increased norgestimate AUC, Cmin and Cmax by 126%, 167% and 108%, respectively. Ethinylestradiol AUC and Cmin decreased by 25% and 44%, and there was no change in Cmax. There was no change in elvitegravir AUC, Cmin and Cmax. The effects of increases in the concentration of norgestimate are not fully known and can include increased risk of insulin resistance. dyslipidemia, acne, and venous thrombosis. In this sense, medical supervision hormonal therapy should be recommended and, if possible, try to avoid cobicistat containing regimens in order to avoid the risk of potential adverse events.

University of Liverpool Recommendation

Potential interaction - may require close monitoring, alteration of drug dosage or timing of administration For more information <u>click here</u>