



Date of report 22 Jun 2020

## Reported case interaction between **Cobicistat** and **Norgestimate**

### Drugs suspected to be involved in the DDI

Perpetrator

**Cobicistat**

Daily Dose

150 (mg)

Dose adjustment performed

No

Administration Route

Oral

Start date

Feb. 11, 2019

End date

Ongoing

Victim

**Norgestimate**

Daily Dose

Unknown

Dose adjustment performed

No

Administration Route

Oral

Start date

Unknown

End date

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

Transgender

Age

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 Ethinyl-estradiol/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, C<sub>min</sub> and C<sub>max</sub> by 126%, 167% and 108%, respectively. Ethinylestradiol AUC and C<sub>min</sub> decreased by 25% and 44%, and there was no change in C<sub>max</sub>. There was no change in elvitegravir AUC, C<sub>min</sub> and C<sub>max</sub>. 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 [click here](#)

