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PHV-issue: Ethinylestradiol

Sehr geehrte Damen und Herren,

In der Sitzung vom Januar 2017 kam das CMDh zu dem Schluss, europaweit die Fach- und Gebrauchsinformation aller Ethinylestradiol-hältigen kombinierten hormonalen Kontrazeptiva zu ändern. (siehe: <http://www.hma.eu/249.html>)



**CMDh RECOMMENDATION
COMBINED HORMONAL CONTRACEPTIVES (CHCs)
CONTAINING ETHINYLESTRADIOL**

Inclusion of a contra indication regarding an interaction between combined hormonal contraceptives containing ethinylestradiol with the medicinal products containing ombitasvir/paritaprevir/ritonavir (Viekirax) and dasabuvir with or without ribavirin agreed by CMDh in January 2017

SmPC

	SmPC for all CHCs containing ethinylestradiol
Section 4.3	<CHC trade name> is contraindicated for concomitant use with the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir, (see sections 4.4 and section 4.5).
Section 4.4	<u>ALT elevations</u> During clinical trials with patients treated for hepatitis C virus infections (HCV) with the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin, transaminase (ALT) elevations higher than 5 times the upper limit of normal (ULN) occurred significantly more frequent in women using ethinylestradiol-containing medications such as combined hormonal contraceptives (CHCs) (see sections 4.3 and 4.5).
Section 4.5	<u>Pharmacodynamic interactions</u> Concomitant use with the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir, with or without ribavirin may increase the risk of ALT elevations (see sections 4.3 and 4.4). Therefore, <CHC trade name>-users must switch to an alternative method of contraception (e.g., progestagen-only contraception or non-hormonal methods) prior to starting therapy with this combination drug regimen. <CHC trade name> can be restarted 2 weeks following completion of treatment with this combination drug regimen.

Package leaflet

	SmPC for all CHCs containing ethinylestradiol
Do not use <CHC trade name>	Do not use <CHC trade name> if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir (see also in section Other medicines and <CHC trade name>).
Other medicines and <CHC trade name>	<p>Do not use <CHC trade name> if you have Hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir as this may cause increases in liver function blood test results (increase in ALT liver enzyme).</p> <p>Your doctor will prescribe another type of contraceptive prior to start of the treatment with these medicinal products.</p> <p><CHC trade name> can be restarted approximately 2 weeks after completion of this treatment. See section “Do not use <CHC trade name>”.</p>