26 July 2018
EMA/CHMP/500340/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Viekirax

Ombitasvir / paritaprevir / ritonavir

On 26 July 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Viekirax. The marketing authorisation holder for this medicinal product is AbbVie Deutschland GmbH & Co. KG.

The CHMP adopted a change to an existing contraindication as follows:[2]

"Patients with **moderate to** severe hepatic impairment (Child-Pugh **B or** C) (see sections 5.2)."

For information, the full contraindications for Viekirax will be as follows:

"Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

Patients with moderate to severe hepatic impairment (Child-Pugh B or C) (see section 5.2).

Use of ethinylestradiol-containing medicinal products such as those contained in most combined oral contraceptives or contraceptive vaginal rings (see section 4.4 and 4.5).

Medicinal products that are highly dependent on CYP3A for clearance and for which elevated plasma levels are associated with serious events must not be co-administered with Viekirax (see section 4.5). Examples are provided below.

CYP3A4 substrates:

- alfuzosin hydrochloride
- amiodarone, disopyramide, dronedarone, quinidine, ranolazine
- astemizole, terfenadine
- cisapride
- colchicine in patients with renal or hepatic impairment
- ergotamine, dihydroergotamine, ergonovine, methylergometrine

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text in bold

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- fusidic acid
- lovastatin, simvastatin, atorvastatin
- lurasidone
- oral midazolam, triazolam
- pimozide
- quetiapine
- salmeterol
- sildenafil (when used for the treatment of pulmonary arterial hypertension)
- ticagrelor

Co-administration of Viekirax with or without dasabuvir with medicinal products that are strong or moderate enzyme inducers is expected to decrease ombitasvir, paritaprevir, and ritonavir plasma concentrations and reduce their therapeutic effect and must not be co-administered (see section 4.5). Examples of contraindicated strong or moderate enzyme inducers are provided below.

Enzyme inducers:

- carbamazepine, phenytoin, phenobarbital
- efavirenz, nevirapine, etravirine
- enzalutamide
- mitotane
- rifampicin
- St. John's Wort (*Hypericum perforatum*)

Co-administration of Viekirax with or without dasabuvir with medicinal products that are strong inhibitors of CYP3A4 is expected to increase paritaprevir plasma concentrations and must not be co-administered with Viekirax (see section 4.5). Examples of contraindicated strong CYP3A4 inhibitors are provided below.

CYP3A4 inhibitors:

- cobicistat
- indinavir, lopinavir/ritonavir, saquinavir, tipranavir,
- itraconazole, ketoconazole, posaconazole, voriconazole
- clarithromycin, telithromycin
- conivaptan"

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.