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Press Office

Press release

European Medicines Agency informs doctors and patients about drug interaction between Victrelis and ritonavir-boosted HIV protease inhibitors

Some combinations no longer recommended; careful monitoring required

The European Medicines Agency has recommended updating the prescribing information for Victrelis (boceprevir) with information about drug interactions between this hepatitis C medicine and the ritonavir-boosted HIV protease inhibitors atazanavir, darunavir and lopinavir.

A drug interaction study in healthy volunteers carried out by Merck Sharp and Dohme, the marketing authorisation holder of Victrelis, found that blood levels of all three HIV medicines were markedly lower than expected when given with Victrelis. It also found that blood levels of Victrelis were markedly lower than expected when given with ritonavir-boosted darunavir or lopinavir, although this effect was not seen with ritonavir-boosted atazanavir.

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the lower blood levels seen in the drug interaction study could mean that the medicines are less effective when given together to patients who are co-infected with hepatitis C and HIV. However, the Committee acknowledged that data from ongoing clinical studies in co-infected patients are needed to assess the clinical impact of these drug-interaction findings on these patients.

Studies on the efficacy and safety of Victrelis when used in patients co-infected with HIV and hepatitis C are ongoing. While data from these studies are awaited, the CHMP has recommended updating the product information to inform prescribers and patients of the findings as a precautionary measure.

Doctors treating patients co-infected with hepatitis C and HIV should be aware of the findings of the drug interaction study. They should not co-administer Victrelis with ritonavir-boosted darunavir or lopinavir in HIV and hepatitis C co-infected patients. Co-administration of Victrelis with ritonavir-boosted atazanavir may be considered on a case-by-case basis if deemed necessary in patients with suppressed HIV viral loads and with an HIV strain without any suspected resistance to the HIV regimen. Increased clinical and laboratory monitoring is warranted.

Patients should not stop taking any of their medicines without talking to their healthcare professional. Patients should contact their healthcare professional if they have any questions or concerns.

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Healthcare professionals in the European Union will receive a letter in the coming days to inform them of the new drug interaction data and the CHMP's recommendations while waiting for further data from ongoing studies in patients co-infected with HIV and hepatitis C.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The CHMP's recommendation will be sent to the European Commission for the adoption of a decision.
3. Victrelis reduced mean trough concentrations of ritonavir-boosted atazanavir, lopinavir and darunavir by 49, 43 and 59 percent, respectively. Mean reductions of 34 to 44 percent and 25 to 36 percent were observed in area under the curve (AUC) and peak concentration (Cmax) of atazanavir, lopinavir and darunavir. Co-administration of ritonavir-boosted atazanavir with Victrelis did not significantly alter the exposure (AUC) of boceprevir, but co-administration of Victrelis with lopinavir/ritonavir or ritonavir-boosted darunavir decreased the AUC of boceprevir by 45 and 32 percent, respectively.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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