17 October 2019
EMA/563896/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Evotaz

atazanavir / cobicistat

On 17 October 2019, 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 Evotaz. The marketing authorisation holder for this medicinal product is Bristol-Myers Squibb Pharma EEIG.

The CHMP adopted two new contraindications restricting co-administration with dabigatran (anticoagulant) and lomipramide (lipid-modifying agent) due to the potential for serious and/or life-threatening adverse reactions.

For information, the full contraindications for Evotaz will be as follows:[2]

> "Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
>
> Co-administration with the following medicinal products that are strong inducers of the CYP3A4 isoform of cytochrome P450 due to the potential for loss of therapeutic effect (see section 4.5):
>
> - carbamazepine, phenobarbital, phenytoin (antiepileptics)
> - St John's wort (Hypericum perforatum) (herbal product)
> - rifampicin (antimycobacterial)
>
> Co-administration with the following medicinal products due to the potential for serious and/or life-threatening adverse reactions (see section 4.5):
>
> - colchicine, when used in patients with renal and/or hepatic impairment (antigout) (see section 4.5)
> - sildenafil - when used for the treatment of pulmonary arterial hypertension (see sections 4.4 and 4.5 for co-administration for the treatment of erectile dysfunction), avanafil (PDE5 inhibitors)
> - **dabigatran (anticoagulant)**
> - simvastatin and lovastatin (HMG-CoA reductase inhibitors) (see section 4.5)
> - **lomitapide (lipid-modifying agent)**

[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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- grazoprevir-containing products, including elbasvir/grazoprevir fixed dose combination (used to treat chronic hepatitis C infection) (see section 4.5)
- glecaprevir/pibrentasvir fixed dose combination (see section 4.5)
- substrates of CYP3A4 or the UGT1A1 isoform of UDP-glucuronyltransferase and have narrow therapeutic windows:
    - alfuzosin (alpha-1-adrenoreceptor antagonist)
    - amiodarone, bepridil, dronedarone, quinidine, systemic lidocaine (antiarrhythmics/antianginals)
    - astemizole, terfenadine (antihistamines)
    - cisapride (gastrointestinal motility agent)
    - ergot derivatives (e.g. dihydroergotamine, ergometrine, ergotamine, methylergonovine)
    - pimozide, quetiapine, lurasidone (antipsychotics/neuroleptics) (see section 4.5)
    - ticagrelor (platelet aggregation inhibitor)
    - triazolam, midazolam administered orally (sedatives/hypnotics) (for caution on parenterally administered midazolam, see section 4.5).

Moderate to severe hepatic impairment."

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.