EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 July 2020
EMA/CHMP/278510/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Reyataz

atazanavir sulphate

On 23 July 2020, 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 Reyataz. The marketing authorisation holder for this medicinal product is Bristol-Myers Squibb Pharma EEIG.

The CHMP adopted a new contraindication as follows:

Co-administration with lomitapide.

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

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

Patients with moderate to severe hepatic insufficiency (see sections 4.2 and 4.4).

Co-administration with simvastatin or lovastatin (see section 4.5).

Combination of rifampicin with concomitant low-dose ritonavir (see section 4.5).

Co-administration of the PDE5 inhibitor sildenafil when used for the treatment of pulmonary arterial hypertension (PAH) only (see section 4.5). For co-administration of sildenafil for the treatment of erectile dysfunction see sections 4.4 and 4.5.

Co-administration with medicinal products that are substrates of the CYP3A4 isoform of cytochrome P450 and have narrow therapeutic windows (e.g., quetiapine, alfuzosin, astemizole, terfenadine, cisapride, pimozide, quinidine, lurasidone, bepridil, triazolam, midazolam administered orally (for caution on parenterally administered midazolam, see section 4.5), lomitapide and ergot alkaloids, particularly, ergotamine, dihydroergotamine, ergonovine, methylergonovine) (see section 4.5).

Co-administration with grazoprevir-containing products, including elbasvir/grazoprevir fixed dose combination (see section 4.5).

Co-administration with glecaprevir/pibrentasvir fixed dose combination (see section 4.5).

[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

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Co-administration with products containing St. John’s wort (*Hypericum perforatum*) (see section 4.5).

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.