25 April 2024
EMA/CHMP/178127/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Reyataz

atazanavir

On 25 April 2024, 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 change to sections 4.3 and 4.5 of the summary of product characteristics (SmPC) to reclassify drug-drug interactions to new contraindications. The new contraindications are:

Co-administration with encorafenib and ivosidenib (see section 4.5).

Co-administration with carbamazepine, phenobarbital, and phenytoin (see section 4.5).

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

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

REYATAZ is contraindicated in patients with severe hepatic insufficiency (see sections 4.2, 4.4 and 5.2). REYATAZ with ritonavir is contraindicated in patients with moderate hepatic insufficiency (see sections 4.2, 4.4, and 5.2).

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

Combination of rifampicin (see section 4.5).

Combination 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, lurasidone, alfuzosin, astemizole, terfenadine, cisapride, pimozide, quinidine, bepridil, triazolam, midazolam

[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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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).

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

Co-administration with apalutamide, encorafenib and ivosidenib (see section 4.5).

Co-administration with carbamazepine, phenobarbital, and phenytoin (see section 4.5).

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