



25 February 2016
EMA/156121/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Telzir

fosamprenavir

On 25 February 2015 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 Telzir. The marketing authorisation holder for this medicinal product is ViiV Healthcare UK Limited.

The CHMP adopted a new contraindication as follows:

"Co-administration of paritaprevir and fosamprenavir/ritonavir is contraindicated due to the expected increase of paritaprevir exposure and the lack of clinical data assessing the magnitude of this increase (see section 4.5)."

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

"Hypersensitivity to fosamprenavir, amprenavir, or ritonavir, or to any of the excipients listed in section 6.1.

Telzir must not be administered concurrently with medicinal products with narrow therapeutic windows that are substrates of cytochrome P450 3A4 (CYP3A4), e.g. alfuzosin, amiodarone, astemizole, bepridil, cisapride, dihydroergotamine, ergotamine, pimozone, quetiapine, quinidine, terfenadine, oral midazolam (for caution on parenterally administered midazolam, see section 4.5), oral triazolam, sildenafil used for the treatment of pulmonary arterial hypertension (for use of sildenafil in patients with erectile dysfunction, see sections 4.4 and 4.5).

Co-administration of paritaprevir and fosamprenavir/ritonavir is contraindicated due to the expected increase of paritaprevir exposure and the lack of clinical data assessing the magnitude of this increase (see section 4.5).

Concomitant use of Telzir with simvastatin or lovastatin is contraindicated because of increased plasma concentrations of lovastatin and simvastatin which can increase the risk of myopathy, including rhabdomyolysis (see section 4.5).

Telzir with ritonavir must not be co-administered with medicinal products with narrow therapeutic windows that are highly dependent on CYP2D6 metabolism, e.g. flecainide and propafenone (see

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



section 4.5).

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

Herbal preparations containing St John's wort (*Hypericum perforatum*) must not be used while taking Telzir due to the risk of decreased plasma concentrations and reduced clinical effects of amprenavir (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.