18 September 2025
EMADOC-1700519818-2433357
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Norvir

ritonavir

On 18 September 2025, 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 Norvir. The marketing authorisation holder for this medicinal product is Abbvie Deutschland GmbH & Co. KG.

The CHMP adopted a change to the existing indication as follows:[2]

~~Ritonavir is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infected patients (adults and children of 2 years of age and older).~~

Ritonavir is indicated as a pharmacokinetic enhancer of co-administered protease inhibitors as part of antiretroviral combination therapy in human immunodeficiency virus-1 (HIV-1) infected patients (adults and children of 2 years of age and older) (see sections 4.2, 4.4, 5.1, 5.2).

The CHMP adopted changes to existing contraindications as follows:[2]

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

~~When ritonavir is used as a pharmacokinetic enhancer of other PIs, consult the Summary of Product Characteristics of the co-administered protease inhibitor for contraindications.~~

Ritonavir should not be given ~~as a pharmacokinetic enhancer or as an antiretroviral agent~~ to patients with decompensated liver disease.

In vitro and *in vivo* studies have demonstrated that ritonavir is a potent inhibitor of CYP3A and CYP2D6- mediated biotransformations. **The enzyme-modulating effect of ritonavir may be dose dependent (see section 5.1).** The following medicines are contraindicated when used with ritonavir and unless otherwise noted, the contraindication is based on the potential for ritonavir to inhibit metabolism of the co-administered medicinal product, resulting in increased

[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, removed text as strikethrough

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exposure to the co-administered medicinal product and risk of clinically significant adverse effects.:

~~The enzyme-modulating effect of ritonavir may be dose dependent. For some products, contraindications may be more relevant when ritonavir is used as an antiretroviral agent than when ritonavir is used as a pharmacokinetic enhancer (e.g. rifabutin and voriconazole):~~

[The table listing contraindicated medicines has been updated to reflect that voriconazole (an antifungal) and rifabutin (an antimycobacterial) are no longer contraindicated when used with ritonavir. The revised table will be provided in section 4.3 of the updated summary of product characteristics (SmPC).]

Detailed recommendations for the use of this product will be described in the updated SmPC, which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.