11 December 2025
EMADOC-1700519818-2658010
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Vfend

voriconazole

On 11 December 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 Vfend. The marketing authorisation holder for this medicinal product is Pfizer Europe MA EEIG.

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.
>
> **Interacting drugs listed in this section and section 4.5 are a guide and not considered a comprehensive list of all possible drugs that may be contraindicated.**
>
> Coadministration of voriconazole is contraindicated with medicinal products that are highly dependent on CYP3A4 for metabolism, and for which elevated plasma concentrations are associated with serious and/or life-threatening reactions (see section 4.5):
>
> - Terfenadine
> - Astemizole
> - Cisapride
> - Pimozide
> - Lurasidone
> - Quinidine
> - Ivabradine
> - Ergot alkaloids (e.g., ergotamine, dihydroergotamine)
> - Sirolimus
> - Naloxegol
> - Tolvaptan
> - Finerenone
> - **Eplerenone**
> - **Voclosporin**

[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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- Venetoclax: Coadministration contraindicated at initiation and during venetoclax dose titration phase.

Coadministration of voriconazole is contraindicated with medicinal products that induce CYP3A4 and significantly reduce voriconazole plasma concentrations:

- Coadministration with rifampicin, carbamazepine, long-acting barbiturates e.g., phenobarbital, and St. John's Wort (see section 4.5).
- Efavirenz:
  Coadministration of standard doses of voriconazole with efavirenz doses of 400 mg once daily or higher is contraindicated (see section 4.5). For information on coadministration of voriconazole and lower doses of efavirenz see section 4.4.
- Ritonavir:
  Coadministration with high-dose ritonavir (400 mg and above twice daily) is contraindicated (see section 4.5). For information on coadministration with lower doses of ritonavir see section 4.4.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (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.