



Summary of Investigation Results

Finerenone Posaconazole Voriconazole

June 11, 2024

Non-proprietary name

- a. Finerenone
- b. Posaconazole
- c. Voriconazole

Brand name (marketing authorization holder)

- a. Kerendia tablets 10 mg, 20 mg (Bayer Yakuhin, Ltd.)
- b. Noxafil Tablets 100 mg, Noxafil for Intravenous Infusion 300 mg (MSD K.K.)
- c. Vfend Tablets 50 mg, 200 mg, Vfend for Intravenous Use 200 mg, Vfend Dry Syrup 2800 mg (Pfizer Japan Inc.), and the others

Japanese market launch

- a. June 2022
- b. April 2020 (Tablets), July 2020 (Intravenous Infusion)
- c. June 2005 (Tablets, Intravenous Use), December 2014 (Dry Syrup)

Indications

See attachment.

Summary of revisions

- a.
- 1. "Patients receiving posaconazole or voriconazole" should be added to the 2.

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CONTRAINDICATIONS (This drug is contraindicated to the following patients.) section.

2. "Posaconazole, voriconazole" should be added to the 10.1 Contraindications for Co-administration (Do not co-administer with the following.) section in 10. INTERACTIONS.
b., c.

1. "Patients receiving finerenone" should be added to the 2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.) section.
2. "Finerenone" should be added to the 10.1 Contraindications for Co-administration (Do not co-administer with the following.) section in 10. INTERACTIONS.

Investigation results and background of the revision

It was concluded in the approval review process that contraindicating co-administration of finerenone with potent CYP3A4 inhibitors is appropriate. It is also known that posaconazole and voriconazole strongly inhibit CYP3A. No additional data such as results of drug-drug interaction studies between finerenone and posaconazole or voriconazole have been obtained after the marketing approval of finerenone. However, it is of concern that strong inhibition of CYP3A by posaconazole or voriconazole may lead to an increased blood concentration of finerenone, thereby causing adverse drug reactions. Therefore, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

Of note, opinions from relevant academic societies were solicited regarding the influence on clinical settings of contraindicating co-administration of finerenone with posaconazole or voriconazole, revealing no specific concerns.



Attachment

| | Brand name | Indications |
|----|---|--|
| a. | Kerendia tablets 10 mg, 20 mg | Chronic kidney disease associated with type 2 diabetes mellitus (excluding patients who have end-stage renal failure or are undergoing dialysis) |
| b. | Noxafil Tablets 100 mg, Noxafil for Intravenous Infusion 300 mg | <ul style="list-style-type: none">•Prophylaxis of deep mycosis in haematopoietic stem cell transplant patients or patients with haematological malignancy who are expected to have neutropenia•Treatment of the following fungal infections Invasive aspergillosis, fusariosis, mucormycosis, coccidioidomycosis, chromoblastomycosis, mycetoma |
| c. | Vfend Tablets 50 mg, 200 mg, Vfend Dry Syrup 2800 mg | <ul style="list-style-type: none">•The following severe or refractory fungal infections<ul style="list-style-type: none">·Invasive aspergillosis, pulmonary aspergilloma, chronic necrotic pulmonary aspergillosis·Candidaemia, oesophageal candidiasis, candida peritonitis, bronchial/pulmonary candidiasis·Cryptococcal meningitis, pulmonary cryptococcosis·Fusariosis·Scedosporiosis•Prophylaxis of deep mycosis in haematopoietic stem cell transplant patients |
| | Vfend for Intravenous Use 200 mg | <ul style="list-style-type: none">•The following severe or refractory fungal infections<ul style="list-style-type: none">·Invasive aspergillosis, pulmonary aspergilloma, chronic necrotic pulmonary aspergillosis·Candidaemia, candida peritonitis, bronchial/pulmonary candidiasis·Cryptococcal meningitis, pulmonary cryptococcosis·Fusariosis·Scedosporiosis•Prophylaxis of deep mycosis in haematopoietic stem cell transplant patients |