Summary of Investigation Results

Voriconazole

November 13, 2024

Non-proprietary name

Voriconazole

Brand name (marketing authorization holder)

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

June 2005 (Tablets, Intravenous Use), December 2014 (Dry Syrup)

Indications

<Vfend Tablets 50 mg, 200 mg, Vfend Dry Syrup 2800 mg>

•The following severe or refractory fungal infections

·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>

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·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

Summary of revisions

1. A statement should be added to the 8. IMPORTANT PRECAUTIONS section that periodic blood electrolyte tests should be performed.
2. “Hyperkalaemia” should be added to the 11.1 Clinically Significant Adverse Reactions section in 11. ADVERSE REACTIONS.

Investigation results and background of the revision

Cases involving hyperkalaemia were evaluated. Cases for which a causal relationship between voriconazole and hyperkalaemia was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

Reference: Number of cases*† and patient mortalities involving hyperkalaemia reported in Japan

A total of 13 cases have been reported to date (including 4 cases for which a causal relationship between the drug and the event was reasonably possible).

No patient mortalities have been reported to date.

*Cases collected in the PMDA's database for adverse drug reactions, etc. reports

†Cases of grade 3 or higher by the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).