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Summary of Investigation Results

Triazolam, posaconazole

July 20, 2022

Non-proprietary name

a. Triazolam

b. Posaconazole

Brand name (Marketing authorization holder)

a. Halcion Tablets 0.125 mg, 0.25 mg (Pfizer Japan Inc.), and the others

b. Noxafil Tablets 100 mg, Noxafil for Intravenous Infusion 300 mg (MSD K.K)

Indications

a. · Insomnia
· Anaesthetic premedication

b. · 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, fusarium infection, mucormycosis, coccidioidomycosis, chromoblastomycosis, mycetoma

Summary of revisions

a.

1. “Posaconazole” should be added to the “patients receiving the following drugs” in the CONTRAINDICATIONS section.
2. “Posaconazole” should be added to the Contraindications for Co-administration section.

b.

1. “Patients receiving triazolam” should be added to the CONTRAINDICATIONS section.
2. “Triazolam” should be added to the Contraindications for Co-administration section.

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Investigation results and background of the revision

Based on the prediction using the mechanistic static pharmacokinetics (MSPK) model with parameters obtained from in vivo data, it was estimated that the plasma exposure of triazolam would increase to a level that causes safety concerns or above when triazolam is co-administered with posaconazole, and it was considered that the risks outweigh the benefits with such increased exposures. As a result of consultation with expert advisors, MHLW/PMDA concluded that revision of Precautions was necessary.

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).

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