This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of Investigation Results

Blonanserin

Posaconazole

December 17, 2021

Non-proprietary name

a. Blonanserin

b. Posaconazole

Branded name (Marketing authorization holder)

a. Lonasen Tablets 2 mg, 4 mg, 8 mg, Lonasen Powder 2%, Lonasen Tapes 20 mg, 30 mg, 40 mg (Sumitomo Dainippon Pharma Co., Ltd.), and the others

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

Indications

a. Schizophrenia

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 “azole antifungal agents” in the CONTRAINDICATIONS section
2. “Posaconazole” should be added to the “azole antifungal agents” of the “drugs that

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strongly inhibit CYP3A4” in the Contraindications for Co-administration section.

b.

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

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 blonanserin would increase to a level that causes safety concerns or above when blonanserin is co-administered with posaconazole, and it was considered that the risks outweigh the benefits with such increased exposures. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

No cases of co-administration of blonanserin and posaconazole have been reported to date.

(Japanese market launch: b: April 2020)

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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