



# Summary of Investigation Results

## Itraconazole

October 12, 2022

### Non-proprietary name

Itraconazole

### Brand name (Marketing authorization holder)

- a. Itrizole Capsules 50 (Janssen Pharmaceutical K.K.), and the others
- b. Itrizole Oral Solution 1% (Janssen Pharmaceutical K.K.), and the others
- c. Itrizole Injection 1% [200 mg] (Janssen Pharmaceutical K.K.)

### Indications

See Attachment.

### Summary of revisions

1. A precaution regarding the periodic blood electrolyte test in the Important Precautions section should be revised to a statement that the test should be performed irrespective of particular conditions for use.
2. "Hypokalaemia" should be added to the Clinically Significant Adverse Reactions section.

### Investigation results and background of the revision

Cases involving hypokalaemia of grade 3 or higher by Common Terminology Criteria for Adverse Events (CTCAE) reported in Japan were evaluated. Cases for which a causal relationship between itraconazole and hypokalaemia was reasonably possible have been reported in Japan, not only in cases with high dose and/or long-term continuous use. As a result of consultation with expert advisors, MHLW/PMDA concluded that revision of Precautions was necessary.

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*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.*

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

A total of 3 cases have been reported to date (including 1 case for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities have been reported to date.

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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Attachment

No.	Brand name	Indications
a.	Itrizole Capsules 50, and the others	<p>&lt;Applicable microorganisms&gt;</p> <p>Dermatophytes (genus <i>Trichophyton</i>, genus <i>Microsporum</i>, genus <i>Epidermophyton</i>), genus <i>Candida</i>, genus <i>Malassezia</i>, genus <i>Aspergillus</i>, genus <i>Cryptococcus</i>, genus <i>Sporothrix</i>, genus <i>Fonsecaea</i></p> <p>&lt;Applicable conditions&gt;</p> <ul style="list-style-type: none"> <li>·Visceral mycosis (deep mycosis) <ul style="list-style-type: none"> <li>Fungemia, respiratory mycosis, gastrointestinal mycosis, urinary tract mycosis, fungal meningitis</li> </ul> </li> <li>·Deep cutaneous mycosis <ul style="list-style-type: none"> <li>Sporotrichosis, chromomycosis</li> </ul> </li> <li>·Superficial cutaneous mycosis (excluding nail tinea) <ul style="list-style-type: none"> <li>Tinea: Body tinea, tinea cruris, tinea manuum, tinea pedis, tinea capitis, kerion celsi, tinea barbae</li> <li>Candidiasis: Oral candidiasis, cutaneous candidiasis, nail candidiasis, candidal paronychia and onychia, candida sycosis, chronic mucocutaneous candidiasis</li> <li>Tinea versicolor, Malassezia folliculitis</li> </ul> </li> </ul>

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No.	Brand name	Indications
		·Nail tinea
b.	Itrazole Oral Solution 1%, and the others	<p>·Fungal infection</p> <p>&lt;Applicable microorganisms&gt;</p> <p>Genus <i>Aspergillus</i>, genus <i>Candida</i>, genus <i>Cryptococcus</i>, genus <i>Blastomyces</i>, genus <i>Histoplasma</i></p> <p>&lt;Applicable conditions&gt;</p> <p>Fungemia, respiratory mycosis, gastrointestinal mycosis, urinary tract mycosis, fungal meningitis, oropharyngeal candidiasis, esophageal candidiasis, blastomycosis, histoplasmosis</p> <p>·Prophylaxis of deep mycosis in patients with haematological malignancy or haematopoietic stem cell transplant patients who are expected to have neutropenia</p>
c.	Itrazole Injection 1% [200 mg]	<p>1. Fungal infection</p> <p>&lt;Applicable microorganisms&gt;</p> <p>Genus <i>Aspergillus</i>, genus <i>Candida</i>, genus <i>Cryptococcus</i>, genus <i>Blastomyces</i>, genus <i>Histoplasma</i></p> <p>&lt;Applicable conditions&gt;</p> <p>Fungemia, respiratory mycosis, gastrointestinal mycosis, urinary tract mycosis, fungal meningitis, esophageal candidiasis, blastomycosis, histoplasmosis</p> <p>2. Febrile neutropenia suspected of fungal infection</p>