



Summary of Investigation Results

Itraconazole

February 15, 2024

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

Japanese market launch

- a. August 1993
- b. September 2006

Indications

See attachment.

Summary of revisions

“Pseudoaldosteronism” should be added to the Clinically Significant Adverse Reactions section in ADVERSE REACTIONS.

Investigation results and background of the revision

Cases involving pseudoaldosteronism were evaluated. Cases for which a causal relationship between itraconazole and pseudoaldosteronism 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.

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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.

Reference: Number of cases* and patient mortalities involving pseudoaldosteronism reported in Japan and overseas

A total of 2 cases have been reported in Japan to date (including 1 case for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities have been reported in Japan to date.

A total of 5 cases have been reported overseas to date (including 4 cases for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities have been reported overseas to date.

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

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).

Brand name	Indications
a. Itrizole Capsules 50	<p><Applicable microorganisms> 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><Applicable conditions></p> <ul style="list-style-type: none"> •Visceral mycosis (deep mycosis) Fungaemia, respiratory mycosis, gastrointestinal mycosis, urinary tract mycosis, fungal meningitis •Deep cutaneous mycosis Sporotrichosis, chromomycosis •Superficial cutaneous mycosis (excluding nail tinea) Tinea: Body tinea, tinea cruris, tinea manuum, tinea pedis, tinea capitis, kerion celsi, tinea barbae Candidiasis: Oral candidiasis, cutaneous candidiasis, nail candida, candidal paronychia and onychia, candidal sycosis, chronic mucocutaneous candidiasis Tinea versicolour, <i>Malassezia</i> folliculitis •Nail tinea
b. Itrizole Oral Solution 1%	<ul style="list-style-type: none"> •Fungal infection <p><Applicable microorganisms></p>

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Brand name	Indications
	<p>Genus <i>Aspergillus</i>, genus <i>Candida</i>, genus <i>Cryptococcus</i>, genus <i>Blastomyces</i>, genus <i>Histoplasma</i> <Applicable conditions> Fungaemia, respiratory mycosis, gastrointestinal mycosis, urinary tract mycosis, fungal meningitis, oropharyngeal candidiasis, oesophageal candidiasis, blastomycosis, histoplasmosis</p> <ul style="list-style-type: none">•Prophylaxis of deep mycosis in patients with haematological malignancy or haematopoietic stem cell transplant patients who are expected to have neutropenia