



# Summary of investigation results

## Itraconazole

January 12, 2016

### Non-proprietary name

Itraconazole

### Brand name (Marketing authorization holder)

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

### Indications

Refer to the attachment below.

### Summary of revision

“Interstitial pneumonia” should be newly added in the Clinically significant adverse reaction section.

### Background of the revision and investigation results

Cases of interstitial pneumonia have been reported in patients treated with itraconazole in Japan. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

### The number of reported adverse reaction and fatal cases in the last 3 fiscal years in Japan

A total of 2 cases associated with interstitial pneumonia have been reported (including 1 case for which a causal relationship to the product could not be ruled out; however, this case was for a condition not included in the approved dosage and administration). No fatality has been reported.



Brand name	Indication
a. Itrazole Capsules 50	<p>&lt;Applicable microorganisms&gt; Dermatophytosis (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>, and genus <i>Fonsecaea</i>.</p> <p>&lt;Applicable conditions&gt;</p> <ol style="list-style-type: none"><li>1. Visceral mycosis (deep mycosis) Fungaemia, respiratory mycosis, gastrointestinal mycosis, urinary tract mycosis, and fungal meningitis.</li><li>2. Deep cutaneous mycosis Sporotrichosis and chromomycosis</li><li>3. Superficial cutaneous mycosis (excluding nail tinea) Tinea Body tinea, tinea cruris, tinea manuum, tinea pedis, tinea capitis, kerion Celsi, and tinea barbae. Candidiasis Oral candidiasis, skin candida, nail candida, candidal paronychia/onychias, candidal sycosis, and chronic mucocutaneous candidiasis. Tinea versicolour and <i>Malassezia</i> folliculitis</li><li>4. Nail tinea</li></ol>
b. Itrazole Oral Solution 1%	<ol style="list-style-type: none"><li>1. Fungal infection &lt;Applicable microorganisms&gt; Genus <i>Aspergillus</i>, genus <i>Candida</i>, genus <i>Cryptococcus</i>, genus <i>Blastomyces</i>, and genus <i>Histoplasma</i>. &lt;Applicable conditions&gt; Fungaemia, respiratory mycosis, gastrointestinal mycosis, urinary tract mycosis, fungal meningitis, oropharyngeal candidiasis, oesophageal candidiasis, blastomycosis, and histoplasmosis.</li><li>2. Febrile neutropenia suspected to be caused by fungal infection</li><li>3. Prophylaxis for deep mycosis among patients with hematological malignancies or hematopoietic stem cell transplant patients predicted to develop neutropenia</li></ol>



*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.*

c. Itrazole Injection 1%	<ol style="list-style-type: none"><li>1. Fungal infection &lt;Applicable microorganisms&gt; Genus <i>Aspergillus</i>, genus <i>Candida</i>, genus <i>Cryptococcus</i>, genus <i>Blastomyces</i>, and genus <i>Histoplasma</i>. &lt;Applicable conditions&gt; Fungaemia, respiratory mycosis, gastrointestinal mycosis, urinary tract mycosis, fungal meningitis, oesophageal candidiasis, blastomycosis, and histoplasmosis.</li><li>2. Febrile neutropenia suspected to be caused by fungal infection</li></ol>
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