



## Summary of investigation results

### Amphotericin B (non-liposome preparation)

July 8, 2014

#### Non-proprietary Name

Amphotericin B

#### Brand Name (Marketing Authorization Holder)

FUNGIZONE for infusion 50 mg (Bristol-Myers K.K.)

#### Indications

Indicated microorganisms:

*Aspergillus*, *Candida*, *Mucor*, *Cryptococcus*, *Blastomyces*, *Histoplasma*, *Coccidioides*,  
*Hormodendrum*, *Phialophora*, and *Hormiscium*

Applicable conditions:

Deep-mycosis by above-mentioned fungi

#### Summary of revision

‘Central nervous system disorder’ should be added in Clinically significant adverse reactions section.

#### Background of the revision and investigation results

Cases of central nervous system disorder have been reported in patients treated with amphotericin B in Japan and foreign countries and a company core data sheet (CCDS)\* has been updated. Following an investigation result based on opinions of expert advisors and 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

No central nervous system disorder-associated cases have been reported in Japan.

---

#### NOTE

\*CCDS is prepared by a marketing authorization holder and covers material relating to safety, indications, dosing, pharmacology, and other information concerning the product.

Pharmaceuticals and Medical Devices Agency

Office of Safety I

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan

E-mail: [safety.info@pmda.go.jp](mailto:safety.info@pmda.go.jp)