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

Fomepizole

November 24, 2015

Non-proprietary name

Fomepizole

Brand name (Marketing authorization holder)

Fomepizole　Intravenous Infusions 1.5 g　“TAKEDA” (Takeda Pharmaceutical Company Limited.)

Indications

Ethylene glycol poisoning, methanol poisoning

Summary of revision

“Clinically significant adverse reaction” subsection should be newly added in the Adverse reaction section in the package insert, and “anaphylaxis” should be newly added in the Clinically significant adverse reaction subsection.

Background of the revision and investigation results

A Case of anaphylaxis has been reported in patient treated with fomepizole overseas. 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 reactions and fatal cases in the last 3 fiscal years in Japan

No case associated with anaphylaxis has been reported.

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