



This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of Precautions Fomepizole

November 24, 2015

Non-proprietary name

Fomepizole

Safety measure

Precautions should be revised in the package insert.

The Clinically significant adverse reaction subsection should be newly added in the Adverse reaction section of the package insert. In this new Clinically significant adverse reaction subsection of the Adverse reactions section, the following text should be added (underlined parts are revised):

Anaphylaxis:

Anaphylaxis may occur. Patients should be carefully monitored. If abnormalities such as dyspnoea, wheezing, and flushing are observed, administration of this drug should be discontinued, and appropriate measures should be adopted.