



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

Clozapine

March 19, 2019

Non-proprietary name

Clozapine

Safety measure

Precautions should be revised in the package insert.

The following language concerning intestinal obstruction and paralytic ileus in the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section should be revised as follows (revised language is underlined):

Intestinal obstruction, paralytic ileus, intestinal ulcer, intestinal perforation:

Cases of intestinal obstruction, paralytic ileus, intestinal ulcer, or intestinal perforation that occurred by the anticholinergic effect of this drug and resulted in mortality have been reported. If any abnormalities such as constipation are observed, appropriate measures should be taken.