

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

Ibrutinib

February 10, 2026

Non-proprietary name

Ibrutinib

Brand name (marketing authorization holder)

Imbruvica Capsules 140 mg (Janssen Pharmaceutical K.K.)

Japanese market launch

May 2016

Indications

- Chronic lymphocytic leukemia (including small lymphocytic lymphoma)
- Primary macroglobulinemia and lymphoplasmacytic lymphoma
- Mantle cell lymphoma
- Chronic graft-versus-host disease after hematopoietic stem cell transplant (for patients who have an inadequate response to steroids)

Summary of revisions

1. A cautionary statement for uveitis should be added to the 8. IMPORTANT PRECAUTIONS section.
2. "Uveitis" should be added to the 11.1 Clinically Significant Adverse Reactions section in 11. ADVERSE REACTIONS.

Investigation results and background of the revision

Cases involving uveitis were evaluated. Cases in which a causal relationship between ibrutinib and uveitis was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of

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revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

Reference: Number of cases* and patient mortalities involving uveitis reported in Japan and overseas

No cases have been reported in Japan to date.

No patient mortalities have been reported in Japan to date.

A total of 14 cases have been reported overseas to date (including 9 cases in which a causal relationship between the drug and the event was reasonably possible).

No patient mortalities have been reported overseas to date.

*: Among the cases collected in the PMDA's safety database for drugs, cases involving uveitis of grade 3 or higher by Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0 for which information on test values of visual acuity and number of anterior chamber cells is included in the case report forms were retrieved.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the "Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency" (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

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