独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

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

Imeglimin hydrochloride

January 13, 2026

Non-proprietary name

Imeglimin hydrochloride

Brand name (marketing authorization holder)

Twymeeg Tablets 500 mg (Sumitomo Pharma Co., Ltd.)

Japanese market launch

September 2021

Indications

Type 2 diabetes mellitus

Summary of revisions

“Severe decreased appetite, vomiting” 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 severe decreased appetite, vomiting were evaluated. Cases in which a causal relationship between imeglimin hydrochloride and severe decreased appetite, vomiting 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 revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

Reference: Number of cases and patient mortalities involving severe decreased appetite, vomiting[*1,2] reported in Japan

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.

A total of 16 cases have been reported to date (including 7 cases in which a causal relationship between the drug and the event was reasonably possible).
No patient mortalities have been reported to date.

*1: Cases collected in the PMDA's safety database for drugs
*2: Among the cases which correspond to MedDRA PT "Decreased appetite" and "Vomiting," cases assessed as CTCAE (ver. 5.0) Grade 3 or higher

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).