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

April 8, 2025

Non-proprietary name

Imeglimin hydrochloride

Brand name (marketing authorization holder)

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

Indications

Type 2 diabetes mellitus

Summary of revisions

- A statement that administration to patients with moderate or severe renal impairment is not recommended should be deleted from 5. PRECAUTIONS CONCERNING INDICATIONS.
- 7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION should be newly added, describing the following: A precautionary statement regarding administration to patients with renal impairment whose eGFR is greater than 10 mL/min/1.73 m^2 and less than 45 mL/min/1.73 m^2; a statement that administration to patients with renal impairment whose eGFR is less than 10 mL/min/1.73 m^2 is not recommended.
- Precautions concerning administration to patients with renal impairment whose eGFR is less than 15 mL/min/1.73 m^2 should be added to 8. IMPORTANT PRECAUTIONS.
- Regarding 9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS, the range of patients with renal impairment for whom administration is not recommended should be changed from patients with eGFR less

than 45 mL/min/1.73 m^2 to those with eGFR less than 10 mL/min/1.73 m^2. In addition, precautions concerning patients with renal impairment whose eGFR is greater than 10 mL/min/1.73 m^2 and less than 45 mL/min/1.73 m^2 should be added.

Investigation results and background of the revision

Taking into account the results of the post-marketing clinical study in patients whose eGFR is less than 45 mL/min/1.73 m^2, as well as other data, the MHLW/PMDA concluded that a revision of PRECAUTIONS was necessary.

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).