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 revisions

Mirogabalin besilate

August 27, 2024

Non-proprietary name

Mirogabalin besilate

Brand name (marketing authorization holder)

Tarlige Tablets 2.5 mg, 5 mg, 10 mg, 15 mg, Talige OD Tablets 2.5 mg, 5 mg, 10 mg, 15 mg (Daiichi Sankyo Co., Ltd.)

Japanese market launch

Tablets: April 2019

OD Tablets: May 2023

Indications

Neuropathic pain

Summary of revisions

“Renal impairment” should be added to the 11.1 Clinically Significant Adverse Reactions section in 11. ADVERSE REACTIONS.

Investigation results and background of the revision

Taking into account the summary of investigation on the risk of kidney function test abnormal using MID-NET® (appendix 1, 2), cases involving renal impairment reported post-marketing, and the situation of issuing precautions in Japan and overseas for the drugs with the same mode of action, the PMDA determined that mirogabalin besilate poses a risk.

As a result of consultation with expert advisors regarding the appropriateness of the above-mentioned PMDA’s opinion, the causality assessment of the reported cases involving renal impairment as well as the necessity of revision of PRECAUTIONS concerning renal

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

Reference: Number of cases*† and patient mortalities involving renal impairment reported in Japan

A total of 26 cases have been reported to date (including 3 cases for which a causal relationship between the drug and event was reasonably possible).

A total of 3 patient mortalities have been reported to date. (A causal relationship between the drug and deaths subsequent to the event could not be established for any of these cases.)

* Cases collected in the PMDA's database for adverse drug reactions, etc. reports

† Cases retrieved by the following conditions:

- •Cases which correspond to MedDRA version 27.0 SMQ “Acute renal failure” (broad) or SOC “Renal and urinary disorders”
- •Cases whose duration of administration of this drug is described
- •Cases with laboratory test results of serum creatinine of 1.07 m/dL or higher for men and 0.79 mg/dL or higher for women, estimated GFR/creatinine clearance of less than 90 mL/min/1.73 m^2, proteinuria 2+ or urinary protein/urine creatinine ratio>0.5 (equivalent to grade 1 or higher by the Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0) after the initiation of administration

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).