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

Zinc acetate hydrate

May 9, 2023

Non-proprietary name

Zinc acetate hydrate

Brand name (marketing authorization holder)

Nobelzin Tablets 25 mg, 50 mg, Nobelzin Granules 5% (Nobelpharma Co., Ltd.), and the others

Japanese market launch

Tablets 25mg, 50mg: February 2015
Granules 5%: February 2023

Indications

•Wilson's disease (hepato-lenticular degeneration)
•Hypozincaemia

Summary of revisions

“Gastric ulcer” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases involving peptic ulcer of grade 3 or higher by the Common Terminology Criteria for Adverse Events (CTCAE v5.0) reported in Japan were evaluated. Cases for which a causal relationship between zinc acetate hydrate and peptic ulcer was reasonably possible have been reported in Japan. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of the Precautions, the MHLW/PMDA concluded that revision was necessary. Of note, it was decided that a precaution for gastric ulcer was appropriate, judging from the sites of ulceration in the

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evaluated cases.

Reference: Number of cases* and patient mortalities involving peptic ulcer reported in Japan

A total of 13 cases involving peptic ulcer have been reported to date (including 7 cases for which a causal relationship between the drug and event was reasonably possible).
One instance of patient mortality has been reported to date. (A causal relationship between the drug and death subsequent to the event could not be established for this case.)

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

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).