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

Thiamazole

June 24, 2025

Non-proprietary name

Thiamazole

Brand name (marketing authorization holder)

Mercazole Tablets 2.5 mg, 5 mg, Mercazole Injection 10 mg (Aska Pharmaceutical Co., Ltd.)

Japanese market launch

Tablets 2.5 mg: February 2021
Tablets 5 mg: July 1956
Injection 10 mg: February 1958

Indications

Hyperthyroidism

Summary of revisions

“Acute pancreatitis” 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 acute pancreatitis and epidemiological literature were evaluated. Cases for which a causal relationship between thiamazole and acute pancreatitis was reasonably possible have been reported, and multiple epidemiological studies suggesting an association between thiamazole and acute pancreatitis have been published. 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.

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Reference: Number of cases* and patient mortalities involving acute pancreatitis reported in Japan

A total of 6 cases have been reported to date (including 5 cases for which a causal relationship between the drug and the event was reasonably possible).

One instance of patient mortality has been reported to date. (A causal relationship between the drug and the death following 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).