



Summary of Investigation Results

Metyrapone

November 21, 2023

Non-proprietary name

Metyrapone

Brand name (marketing authorization holder)

Metopiron Capsules 250 mg (Ceolia Pharma Co., Ltd.)

Japanese market launch

September 1965

Indications

- Measurement of pituitary ACTH secretory reserve capacity
- Cushing's syndrome

Summary of revisions

1. A precautionary statement regarding prolonged QT should be added to the IMPORTANT PRECAUTIONS section, and "prolonged QT" should be added to the Other Adverse Reactions section in ADVERSE REACTIONS.
2. A precautionary statement regarding hypokalaemia should be added to the IMPORTANT PRECAUTIONS section, and "hypokalaemia" should be added to the Other Adverse Reactions section in ADVERSE REACTIONS.

Investigation results and background of the revision

Cases involving prolonged QT in an overseas clinical study and post-marketing cases involving hypokalaemia were evaluated. Cases for which a causal relationship between metyrapone and prolonged QT or hypokalaemia was reasonably possible have been

Pharmaceuticals and Medical Devices Agency

reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS as well as the consideration of the precautionary statements for a similar drug, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

Reference: Number of cases* and patient mortalities involving prolonged QT and hypokalaemia reported in Japan and overseas

Cases involving prolonged QT

No cases have been reported in Japan to date.

Cases involving hypokalaemia

A total of 2 cases have been reported in Japan to date (including 1 case for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities have been reported in Japan to date.

Cases involving prolonged QT

No cases have been reported overseas to date.

Cases involving hypokalaemia

A total of 4 cases have been reported overseas to date. (A causal relationship between the drug and event could not be established for these cases.)

No patient mortalities have been reported overseas to date.

*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).