

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

Colchicine

February 24, 2026

Non-proprietary name

Colchicine

Brand name (marketing authorization holder)

Colchicine Tablets 0.5 mg "Takata"
(TAKATA Pharmaceutical Co., Ltd.)

Japanese market launch

November 1964

Indications

Relief and prophylaxis of gout attacks
Familial mediterranean fever

Summary of revisions

1. A description to the effect that cases of serious toxic symptoms that resulted in death have been reported should be added to the 1. WARNINGS.
2. A description to the effect that, when this drug is used for relief of gout attacks, administration at high doses exceeding 1.5 mg/day should be avoided unless clinically warranted, and that the latest Japanese guideline should be used as a reference for the one-time dose, daily dose, and administration duration, as well as a description to the effect that this drug should not be administered at a dose exceeding the approved dosage when used for prophylaxis of gout attacks or the treatment of familial mediterranean fever, should be added to the 7. PRECAUTIONS CONCERNING

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
Contact: <https://www.pmda.go.jp/english/contact/0001.html>



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.

DOSAGE AND ADMINISTRATION.

3. A description to the effect that, if any toxic symptoms occur, patients should be instructed to seek medical attention should be added to the 8. IMPORTANT PRECAUTIONS.
4. A description to the effect that administration to patients with severe renal impairment should be avoided unless clinically warranted should be added to the 9.2 Patients with Renal Impairment section in the 9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS. In addition, a description to the effect that administration duration should be limited to the minimum necessary when this drug is administered to patients with renal impairment should be added.
5. "Symptoms of colchicine poisoning" should be added to the 11.1 Clinically Significant Adverse Reactions section in the 11. ADVERSE REACTIONS.

Investigation results and background of the revision

Fatal cases were mainly evaluated. Among cases of suspected symptoms of colchicine poisoning, multiple cases in which [1] colchicine was administered at a high dose (exceeding 1.8 mg/day) although a precautionary statement that the daily dosage should be limited to 1.8 mg had been provided, and a case in which [2] colchicine was administered to patients with severe renal impairment, although the administered dose was low (1 mg/day), have been reported. A causal relationship between colchicine and symptoms of colchicine poisoning in these cases was reasonably possible. 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. The dose for which caution should be exercised was set to be a dose that exceeds 1.5 mg, which is a feasible dosage based on the specification for this drug (0.5 mg tablet). (The daily dosage is also specified as 1.5 mg in the Guidelines for the Management of Hyperuricemia and Gout: 3rd Edition [Supplement Version 2022].)

Reference: Number of patient mortalities*¹ after colchicine administration reported in Japan

A total of 18 patient mortalities have been reported to date (including 8 cases in which a causal relationship between the drug and the event*² was reasonably possible).



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.

A total of 18 patient mortalities have been reported to date (including 8 cases in which a causal relationship between the drug and the death following the event^{*2} was reasonably possible).

*1: Cases collected in the PMDA's safety database for drugs

*2: The causal relationship with symptoms of colchicine poisoning was evaluated.

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).

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
Contact: <https://www.pmda.go.jp/english/contact/0001.html>