Revision of PRECAUTIONS

Colchicine

February 24

Therapeutic category

Gout preparations

Non-proprietary name

Colchicine

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revision
(N/A)	1. WARNINGS Cases of serious toxic symptoms (gastrointestinal disorder, blood disorder, renal disorder, liver disorder, etc.) that resulted in death have been reported in patients who received this drug at high doses exceeding the daily dose of this drug of 1.5 mg and in patients with severe renal impairment. Administration of doses higher than 1.5 mg/day or administration to patients with severe renal impairment should be avoided unless clinically warranted. In addition, if any symptoms such as nausea/vomiting, abdominal pain, diarrhoea, burning sensation in the pharynx/stomach/skin, haematuria, oliguria, muscle weakness, etc. occur, patients should be instructed to seek medical attention immediately.
7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION < Relief and prophylaxis of gout attack > Starting this drug earlier after the onset of a gout attack is more effective. Acute toxic symptoms may occur within several hours after administration when this drug is administered at a high dose or misused. The dosage and administration should be strictly followed, and attention should be paid to the following matters.	7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION < Common to all indications > Since the frequency of occurrence of gastrointestinal disorders, such as diarrhoea, etc. increases as the dose increases, the following matters should be noted. Cases of serious toxic symptoms (gastrointestinal disorder, blood disorder, renal disorder, liver disorder, etc.) that occurred after administration at high doses exceeding the daily dose of 1.5 mg and resulted in death have been reported.

・ For treatment of gout attack, 0.5 mg is administered every 3 to 4 hours until the pain attack is relieved. Since the frequency of occurrence of gastrointestinal disorders, such as diarrhoea, etc. increases as the dose increases, the daily dose should preferably be limited to 1.8 mg. ・ This drug should preferably be taken as soon as possible when an antecedent sign occurring 3 to 4 hours before attack is detected. Long-term prophylactic administration for gout attack is not recommended because it may cause serious adverse reactions such as blood disorder, genital disorder, liver/renal disorder, alopecia, etc. and is of limited usefulness.	・ When this drug is used for the relief of a gout attack, administration at high doses exceeding 1.5 mg/day should be avoided unless clinically warranted. For the one-time dose, daily dose, and administration duration, the latest Japanese guideline should be used as a reference. ・ This drug should not be administered at a dose exceeding the approved dosage when used for the prophylaxis of gout attack or the treatment of familial mediterranean fever. Acute toxic symptoms may occur within several hours after administration when this drug is administered at a high dose or misused. < Relief of gout attack > Starting medication earlier after the onset of a gout attack is more effective. In addition, administration of this drug should be discontinued as soon as the pain improves. < Prophylaxis of gout attack > Long-term prophylactic administration for gout attack is not recommended because it may cause serious adverse reactions such as blood disorder, genital disorder, liver/renal disorder, alopecia, etc. and is of limited usefulness.

	This drug should preferably be taken as soon as possible when an antecedent sign occurring 3 to 4 hours before the attack is detected.
8. IMPORTANT PRECAUTIONS (N/A)	8. IMPORTANT PRECAUTIONS Symptoms of colchicine poisoning may occur in patients who have received high-dose administration or in patients with renal impairment. If any symptoms such as nausea/vomiting, abdominal pain, diarrhoea, burning sensation in the pharynx/stomach/skin, haematuria, oliguria, muscle weakness, etc. occur, patients should be instructed to seek medical attention immediately.
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.2 Patients with Renal Impairment (N/A)	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.2 Patients with Renal Impairment Patients with severe renal impairment who are not receiving any of the concomitant drugs described in 9.2.1 Administration of this drug should be avoided unless clinically warranted. When this drug is administered, care should be taken by starting at a very low dose and limiting the administration duration to the minimum necessary, etc. Cases of serious toxic symptoms that resulted in death have been reported in patients with severe renal impairment.
Patients with renal impairment who are not receiving any of the	Patients with renal impairment who are not receiving any of the

concomitant drugs described in 9.2.1 When this drug is administered, the administration should be started at a very low dose. Plasma concentration of this drug may increase and serious adverse reactions may occur early.	concomitant drugs described in 9.2.1 (excluding patients with severe renal impairment) When this drug is administered, care should be taken by starting at a very low dose and limiting the administration duration to the minimum necessary, etc. Plasma concentration of this drug may increase and serious adverse reactions may occur early.
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Symptoms of colchicine poisoning Symptoms of colchicine poisoning may occur as a result of increased blood concentration of this drug in patients who received this drug at high doses or in patients with renal impairment, etc., even if the doses are within the range of the approved dosage and administration. If toxic symptoms such as gastrointestinal disorder, blood disorder, renal disorder, liver disorder, etc. are observed, administration of this drug should be discontinued, and appropriate measures should be taken. Measures: Fluid replacement for dehydration, correction of electrolytes, symptomatic treatment for cytopenia, infection, and coagulation abnormalities, and management of blood pressure and respiratory conditions should be performed. This drug is not eliminated by forced diuresis or haemodialysis.

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.

【REFERENCES】Guidelines for the Management of Hyperuricemia and Gout: 3rd Edition (Supplement to 2022)
https://minds.jcqhc.or.jp/common/summary/pdf/c00476_supplementary.pdf