

Published by
Ministry of Health, Labour and Welfare



Translated by
Pharmaceuticals and Medical Devices Agency



This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of PRECAUTIONS

Warfarin potassium

November 21, 2023

Therapeutic category

Anticoagulants

Non-proprietary name

Warfarin potassium

Safety measure

PRECAUTIONS should be revised.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director-General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions):

Revised language is underlined.

Current	Revision
Adverse Reactions Clinically Significant Adverse Reactions (N/A)	Adverse Reactions Clinically Significant Adverse Reactions <u>Acute kidney injury:</u> <u>Acute kidney injury may occur after administration of oral anticoagulants. Among cases of acute kidney injury after administration of warfarin, cases in which haematuria and/or supratherapeutic INR were noted or a renal biopsy showed numerous red cell casts in the renal tubules have been reported.</u>

[References] Brodsky, S., et al.: J. Am. Soc. Nephrol. 2018; 29: 2787-2793

Zakrocka, I., et al.: Adv. Clin. Exp. Med. 2022; 31: 165-173

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

Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, PSEHB Notification No. 0611-1 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions):

Revised language is underlined.

Current	Revision
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Acute kidney injury</u> <u>Acute kidney injury may occur after administration of oral</u>

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
 E-mail: safety.info@pmda.go.jp

	<u>anticoagulants. Among cases of acute kidney injury after administration of warfarin, cases in which haematuria and/or supratherapeutic INR were noted or a renal biopsy showed numerous red cell casts in the renal tubules have been reported.</u>
--	--

[References] Brodsky, S., et al.: J. Am. Soc. Nephrol. 2018; 29: 2787-2793

Zakrocka, I., et al.: Adv. Clin. Exp. Med. 2022; 31: 165-173

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

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp