

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

Arsenic trioxide

February 25, 2020

Therapeutic category

Antineoplastics-miscellaneous

Non-proprietary name

Arsenic trioxide

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

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

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>Wernicke's encephalopathy:</u> <u>Wernicke's encephalopathy may occur. Patients should be carefully monitored and if symptoms such as disturbed consciousness, ataxia, and eye movement disorder are observed, vitamin B1 measurement and imaging diagnostic assessment using MRI should be performed and appropriate measures should be taken such as administration of vitamin B1 and discontinuing this drug.</u>

N/A: Not Applicable, because the section is not included in the current package insert.

Pharmaceuticals and Medical Devices Agency

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