



Summary of Investigation Results

Arsenic trioxide

February 25, 2020

Non-proprietary name

Arsenic trioxide

Branded name (Marketing authorization holder)

Trisenox Injection 10 mg (Nippon Shinyaku Co., Ltd.)

Indications

Recurrent or refractory acute promyelocytic leukemia

Summary of revisions

“Wernicke's encephalopathy” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of Wernicke's encephalopathy have been reported overseas in patients treated with arsenic trioxide. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary. Although no corresponding cases have been reported in Japan, revision based on overseas cases was determined appropriate by considering that currently there have been no findings to indicate ethnic differences in the safety profile of the drug between Japanese and overseas patients and the drug is indicated for “recurrent or refractory acute promyelocytic leukemia” in Japan for which extremely few patients are found in Japan.



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.

Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

No cases involving Wernicke's encephalopathy have been reported to date.

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).