Summary of Investigation Results

Cytarabine (excluding 400 mg and 1 g preparations)

October 6, 2020

Non-proprietary name

Cytarabine

Branded name (Marketing authorization holder)

Cylocide Injection 20 mg, 40 mg, 60 mg, 100 mg, 200 mg (Nippon Shinyaku Co., Ltd.)

Indications

- Acute leukaemia (including erythroleukaemia and cases of chronic myeloid leukaemia transformation)
- Gastrointestinal carcinoma (gastric cancer, pancreatic carcinoma, hepatic cancer, colon cancer, etc.), lung cancer, breast cancer, female genital cancer (uterine cancer, etc.), etc., only when co-administered with other antitumor agents (such as fluorouracil, mitomycin C, cyclophosphamide hydrate, methotrexate, vincristine sulfate, and vinblastine sulfate).
- Bladder tumour

Summary of revisions

1. Language concerning cytarabine syndrome should be added to the IMPORTANT PRECAUTIONS section.
2. “Cytarabine syndrome” should be added to the Clinically Significant Adverse Reactions section.
3. The language concerning cytarabine syndrome in the OVERDOSAGE section should be deleted.

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.

Investigation results and background of the revision

Cases of cytarabine syndrome have been reported in patients treated with cytarabine in Japan. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

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

A total of 2 cases involving cytarabine syndrome have been reported to date. (A causal relationship between the drug and event was reasonably possible for both cases.)
No patient mortalities 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).

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