独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

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Summary of Investigation Results

Cytarabine
Daunorubicin hydrochloride

February 10, 2026

Non-proprietary name

a. Cytarabine

b. Daunorubicin hydrochloride

Brand name (marketing authorization holder)

a. Cylocide Injection 20 mg, 40 mg, 60 mg, 100 mg, 200 mg, Cylocide N Injection 400 mg, 1 g (Nippon Shinyaku Co., Ltd.), and the others

b. DAUNOMYCIN FOR INJECTION 20 mg (Meiji Seika Pharma Co., Ltd.)

Japanese market launch

a. Cylocide Injection 20 mg: April 1971
Cylocide Injection 40 mg, 60 mg: November 1971
Cylocide Injection 100 mg, 200 mg: October 1987
Cylocide N Injection 400 mg: April 2000
Cylocide N Injection 1 g: April 2010

b. DAUNOMYCIN FOR INJECTION 20 mg: August 1970

Indications

a. < Cylocide Injection 20 mg, 40 mg, 60 mg, 100 mg, 200 mg >

• Acute leukaemia (including erythroleukaemia and cases of chronic myeloid leukaemia transformation)

• Gastrointestinal carcinoma (gastric cancer, pancreatic carcinoma, hepatic cancer, colon cancer, and the others), lung cancer, breast cancer, female genital cancer (uterine cancer, and the others), and the others, only when co-administered with other antitumor agents

(fluorouracil, mitomycin C, cyclophosphamide hydrate, methotrexate, vincristine sulfate, vinblastine sulfate, and the others).

• Bladder tumour

< Cylocide N Injection 400 mg, 1 g >

• High-dose cytarabine therapy

The following therapies for acute leukaemia (acute myeloid leukaemia, acute lymphocytic leukaemia)

- Remission induction therapy for relapsed or refractory cases (salvage therapy)
- Consolidation therapy

Relapsed or refractory malignant lymphoma

Only when co-administered with other antitumor agents for acute lymphocytic leukaemia and malignant lymphoma

• Pretreatment for tumour-specific T-cell infusion therapy

b. Acute leukaemia (including chronic myeloid leukaemia transformation)

Summary of revisions

1. A statement regarding tumour lysis syndrome should be added to 8. IMPORTANT PRECAUTIONS section.
2. “Tumour lysis syndrome” should be added to the 11.1 Clinically Significant Adverse Reactions section in 11. ADVERSE REACTIONS.

Investigation results and background of the revision

Cases involving tumour lysis syndrome were evaluated. Cases in which a causal relationship between tumour lysis syndrome and cytarabine or daunorubicin hydrochloride was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

Reference: Number of cases* and patient mortalities involving tumour lysis syndrome reported in Japan

a. A total of 7 cases have been reported to date (including 4 cases in which a causal relationship between the drug and the event was reasonably possible).

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No patient mortalities have been reported to date.

b. A total of 10 cases have been reported to date (including 4 cases in which a causal relationship between the drug and the event was reasonably possible).

One instance of patient mortality has been reported to date. (A causal relationship between the drug and the death following the event was reasonably possible for this case.)

*: Among the cases collected in the PMDA's safety database for drugs, those for which blood test results for 2 or more of the following items (uric acid, potassium, phosphorus, and calcium) were documented in the case report forms were retrieved.

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).