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Summary of Investigation Results

Gemcitabine hydrochloride

December 17, 2024

Non-proprietary name

Gemcitabine hydrochloride

Brand name (marketing authorization holder)

Gemzar Injection 200 mg, 1 g (Eli Lilly Japan K.K.), and the others

Japanese market launch

August 1999

Indications

•Non-small cell lung cancer.
•Pancreatic carcinoma
•Biliary carcinoma
•Urothelial carcinoma
•Inoperable or recurrent breast cancer
•Ovarian cancer that has progressed after cancer chemotherapy
•Relapsed or refractory malignant lymphoma

Summary of revisions

“Toxic epidermal necrolysis (TEN)” and “oculomucocutaneous syndrome (Stevens-Johnson 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 toxic epidermal necrolysis and oculomucocutaneous syndrome were evaluated. Cases for which a causal relationship of gemcitabine hydrochloride to toxic

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epidermal necrolysis or oculomucocutaneous syndrome 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 toxic epidermal necrolysis reported in Japan and overseas

A total of 2 cases have been reported in Japan to date (including 1 case for which a causal relationship between the drug and the event was reasonably possible).
No patient mortalities have been reported in Japan to date.

A total of 21 cases have been reported overseas to date (including 2 cases for which a causal relationship between the drug and the event was reasonably possible).
A total of 4 patient mortalities have been reported overseas to date. (A causal relationship between the drug and death subsequent to the event could not be established for any of these cases.)

Number of cases* and patient mortalities involving oculomucocutaneous syndrome reported in Japan and overseas

A total of 6 cases have been reported in Japan to date (including 1 case for which a causal relationship between the drug and the event was reasonably possible).
No patient mortalities have been reported in Japan to date.

A total of 12 cases have been reported overseas to date. (A causal relationship between the drug and the event was reasonably possible for 3 cases, including 1 case in which the drug was administered outside the approved indications.)
One instance of patient mortality has been reported overseas to date. (A causal relationship between the drug and death subsequent to the event could not be established for this case.)

* Cases collected in the PMDA's database for adverse drug reactions, etc. reports
† Cases with information related to the diagnostic criteria (skin eruption, pyrexia, skin biopsy),

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as documented in the case report form

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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