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Summary of investigation results

Panitumumab

March 24, 2015

Non-proprietary name

Panitumumab (genetical recombination)

Brand name (Marketing authorization holder)

Vectibix Intravenous Infusions 100 mg and 400 mg (Takeda Pharmaceutical Company Limited)

Indications

KRAS wild-type, incurable, unresectable, advanced/recurrent colorectal cancer

Summary of revision

'Oculomucocutaneous syndrome (Stevens–Johnson syndrome)' should be added in the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of adverse events suggestive of oculomucocutaneous syndrome (Stevens–Johnson syndrome) have been reported in patients treated with panitumumab in Japan and in foreign countries, and the company core datasheet (CCDS)* has been revised to include information on oculomucocutaneous syndrome (Stevens–Johnson syndrome). Following an investigation based on the opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A total of 2 cases of adverse events suggestive of oculomucocutaneous syndrome have been reported (including 2 cases in which causality could not be ruled out). No fatalities have been reported.

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Office of Safety I
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NOTE:

*The CCDS is prepared by the marketing authorization holder and covers material relating to safety, indications, dosing, pharmacology, and other information concerning the product.

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