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Summary of Investigation Results

Fruquintinib

February 10, 2026

Non-proprietary name

Fruquintinib

Brand name (marketing authorization holder)

Fruzaqla capsules 1 mg, 5 mg (Takeda Pharmaceutical Company Limited)

Japanese market launch

November 2024

Indications

Unresectable, advanced or recurrent colorectal cancer that has progressed after cancer chemotherapy

Summary of revisions

1. A cautionary statement for nephrotic syndrome should be added to the 8. IMPORTANT PRECAUTIONS section.
2. "Nephrotic 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 nephrotic syndrome were evaluated. Cases in which a causal relationship between fruquintinib and nephrotic 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.



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

A total of 11 cases have been reported to date (including 3 cases in which a causal relationship between the drug and the event was reasonably possible).

No patient mortalities have been reported to date.

*: Cases collected in the PMDA's safety database for drugs

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).

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
Contact: <https://www.pmda.go.jp/english/contact/0001.html>