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

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.

Summary of Investigation Results

Nemolizumab (genetical recombination)

May 20, 2025

Non-proprietary name

Nemolizumab (genetical recombination)

Brand name (marketing authorization holder)

Mitchga Vials 30 mg, Mitchga Syringes 60 mg (Maruho Co., Ltd.)

Japanese market launch

Mitchga Vials 30 mg: June 2024

Mitchga Syringes 60 mg: August 2022

Indications

<Mitchga Vials 30 mg>

Treatment of the following diseases in patients who have had an inadequate response to conventional treatments:

•Pruritus associated with atopic dermatitis

•Prurigo nodularis

<Mitchga Syringes 60 mg>

Pruritus associated with atopic dermatitis (only for patients who have had an inadequate response to conventional treatments)

Summary of revisions

“Pemphigoid” 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 pemphigoid were evaluated. Cases for which a causal relationship between

nemolizumab (genetical recombination) and pemphigoid 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 pemphigoid reported in Japan and overseas

A total of 17 cases have been reported in Japan to date (including 2 cases 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 2 cases have been reported overseas to date. (A causal relationship between the drug and the event was reasonably possible for these cases.)
No patient mortalities have been reported overseas to date.

*Cases collected in the PMDA's database for adverse drug reactions, etc. reports

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).