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

Adalimumab (genetical recombination) [including biosimilars]

September 9, 2025

Non-proprietary name

Adalimumab (genetical recombination) and follow-on biologics (biosimilars)

Brand name (marketing authorization holder)

Humira 20 mg for S.C. Injection Syringe 0.2 mL, Humira 40 mg for S.C. Injection Syringe 0.4 mL, Humira 80 mg for S.C. Injection Syringe 0.8 mL, Humira 40 mg for S.C. Injection Pen 0.4 mL, Humira 80 mg for S.C. Injection Pen 0.8 mL (AbbVie GK), and follow-on biologics (biosimilars)

Japanese market launch

June 2008*[1]

Indications

Humira 20 mg for S.C. Injection Syringe 0.2 mL
Humira 40 mg for S.C. Injection Syringe 0.4 mL
Humira 40 mg for S.C. Injection Pen 0.4 mL

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

•Polyarticular juvenile idiopathic arthritis

Humira 20 mg for S.C. Injection Syringe 0.2 mL
Humira 40 mg for S.C. Injection Syringe 0.4 mL
Humira 80 mg for S.C. Injection Syringe 0.8 mL
Humira 40 mg for S.C. Injection Pen 0.4 mL
Humira 80 mg for S.C. Injection Pen 0.8 mL

•Treatment of moderate or severe ulcerative colitis (only in patients who have had an inadequate response to conventional treatments)

Humira 40 mg for S.C. Injection Syringe 0.4 mL

Humira 40 mg for S.C. Injection Pen 0.4 mL

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

•Non-radiographic axial spondyloarthritis

Humira 40 mg for S.C. Injection Syringe 0.4 mL

Humira 80 mg for S.C. Injection Syringe 0.8 mL

Humira 40 mg for S.C. Injection Pen 0.4 mL

Humira 80 mg for S.C. Injection Pen 0.8 mL

•Rheumatoid arthritis (including the prevention of structural joint damage)

•Hidradenitis suppurativa

•Pyoderma gangrenosum

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

•Psoriasis vulgaris, psoriatic arthritis, pustular psoriasis

•Ankylosing spondylitis

•Intestinal Behcet's disease

•Non-infectious intermediate uveitis, posterior uveitis, and panuveitis

•Remission induction therapy and maintenance therapy for moderate to severe active Crohn's disease (only in patients who have had an inadequate response to conventional treatments)

Summary of revisions

"Autoimmune hepatitis" 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 autoimmune hepatitis were evaluated. Cases in which a causal relationship between adalimumab (genetical recombination) and autoimmune hepatitis 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

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.

MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

Reference: Number of cases*2 and patient mortalities involving autoimmune hepatitis reported in Japan and overseas

A total of 4 cases have been reported in Japan to date. (A causal relationship between the drug and the event could not be established for any of these cases.)
No patient mortalities have been reported in Japan to date.

A total of 13 cases have been reported overseas*3 to date (including 4 cases in which a causal relationship between the drug and the event was reasonably possible).
No patient mortalities have been reported overseas to date.

*1 The oldest month and year of the Japanese market launch among the drug products, including discontinued products, are described.
*2 Cases collected in the PMDA's safety database for drugs
*3 Cases that were presented as the basis for a revision of the Company Core Data Sheet (CCDS) by the marketing authorization holder

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).