



Summary of Investigation Results

Leflunomide

May 9, 2023

Non-proprietary name

Leflunomide

Brand name (marketing authorization holder)

Arava Tablets 10 mg, 20 mg, 100 mg (Sanofi K.K.)

Japanese market launch

September 2003

Indications

Rheumatoid arthritis

Summary of revisions

- "Skin ulcer" should be added to the statement in the Important Precautions section (old instructions) that administration of this drug should be discontinued and a drug elimination procedure should be preferably performed if serious adverse reaction occurs.
- "Skin ulcer" should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases involving skin ulcer reported in Japan and overseas were evaluated. Cases for which a causal relationship between leflunomide and skin ulcer was reasonably possible have been reported overseas. As a result of consultation with expert advisors, the MHLW/PMDA concluded that revision of Precautions was necessary.

Reference: Number of cases*[†] and patient mortalities involving skin ulcer reported in Japan and overseas

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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.

One case has been reported in Japan to date. (A causal relationship between the drug and event could not be established for this case.)

No patient mortalities have been reported in Japan to date.

A total of 8 cases have been reported overseas to date. (A causal relationship between the drug and event was reasonably possible for 5 cases, including 2 cases in which the drug was administered outside the indications approved in Japan.)

No patient mortalities have been reported overseas to date.

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

†Cases which were presented as the basis for a revision of 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).