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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Summary of Investigation Results

Mesalazine
Salazosulfapyridine

September 9, 2025

Non-proprietary name

Mesalazine

Salazosulfapyridine

Brand name (marketing authorization holder)

See attachment.

Japanese market launch

See attachment.

Indications

See attachment.

Summary of revisions

“Anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis” 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 vasculitis were evaluated. Cases in which a causal relationship between anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis and mesalazine or salazosulfapyridine 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.

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

a. to c.

A total of 17 cases have been reported to date (including 6 cases in which a causal relationship between the drug and the event was reasonably possible).

No patient mortalities have been reported to date.

d., e.

A total of 4 cases have been reported to date. (A causal relationship between the drug and the event was reasonably possible for 2 cases, including 1 case in which the drug was administered outside the approved indications.)

One instance of patient mortality has been reported to date. (A causal relationship between the drug and the death following the event could not be established for this case.)

*Cases meeting both of the following conditions were retrieved from those collected in the PMDA's safety database for drugs:

•Cases that fell under MedDRA ver.28.0 SMQ “Vasculitis (broad)”

•Cases for which it was documented in the case report forms that the patient tested positive for anti-neutrophil cytoplasmic antibody (ANCA)

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).

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Attachment

No.	Non-proprietary name	Brand name	Marketing authorization holder	Japanese market launch	Indications
a.	Mesalazine	Asacol tablets 400 mg and the others	Zeria Pharmaceutical Co., Ltd. and the others	December 2009	Ulcerative colitis (excluding severe cases)
b.	Mesalazine	Pentasa Tablets 250 mg, 500 mg, Pentasa Granules 94%, Pentasa Suppositories 1 g, Pentasa Enema 1 g, and the others	Ferring Pharmaceuticals Co., Ltd. and the others	Tablets 250 mg: July 1996 Tablets 500 mg: October 2008 Granules: December 2015 Suppositories: June 2013 Enema: June 2003	[Tablets, Granules] Ulcerative colitis (excluding severe cases), Crohn's disease [Suppositories, Enema] Ulcerative colitis (excluding severe cases)
c.	Mesalazine	Lialda Tablets 600 mg, 1200 mg	Mochida Pharmaceutical Co. Ltd.	Tablets 600 mg: September 2025 Tablets 1200 mg: November 2016	Ulcerative colitis (excluding severe cases)
d.	Salazosulfapyridine	Salazopyrin Tablets 500 mg, Salazopyrin Suppositories 500 mg	Pfizer Japan Inc.	Tablets: September 1969 Suppositories: June 1982	[Tablets] Ulcerative colitis, regional enteritis, non-specific colitis [Suppositories] Ulcerative colitis
e.	Salazosulfapyridine	Azulfidine EN tablets 250 mg, 500 mg, and the others	AYUMI Pharmaceutical Corporation and the others	Tablets 250 mg: August 2002 Tablets 500 mg: December 1995	Rheumatoid arthritis