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

Mesalazine

May 9, 2023

Non-proprietary name

Mesalazine

Brand name (marketing authorization holder)

a. Lialda Tablets 1200 mg (Mochida Pharmaceuticals Co. Ltd.)
b. Asacol tablets 400 mg (Zeria Pharmaceutical Co., Ltd.)
c. Pentasa Tablets 250 mg, 500 mg, Pentasa Granules 94%, Pentasa Suppositories 1 g, Pentasa Enema 1 g (Kyorin Pharmaceutical Co., Ltd.)
and the others

Japanese market launch

a. Lialda Tablets 1200 mg: November 2016
b. Asacol tablets 400 mg: December 2009
c. Pentasa Tablets 250 mg: July 1996, 500 mg: October 2008, Pentasa Granules 94%: December 2015, Pentasa Suppositories 1 g: June 2013, Pentasa Enema 1 g: June 2003

Indications

a. Lialda Tablets 1200 mg, b. Asacol tablets 400 mg, c. Pentasa Suppositories 1 g, Pentasa Enema 1 g: Ulcerative colitis (excluding severe cases)
c. Pentasa Tablets 250 mg, 500 mg, Pentasa Granules 94%: Ulcerative colitis (excluding severe cases), Crohn's disease

Summary of revisions

“Toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson syndrome), and drug-induced hypersensitivity syndrome” should be added to the Clinically Significant Adverse Reactions section.

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Investigation results and background of the revision

Cases involving toxic epidermal necrolysis, oculomucocutaneous syndrome, or drug-induced hypersensitivity syndrome reported in Japan were evaluated. Cases for which a causal relationship between mesalazine and epidermal necrolysis, oculomucocutaneous syndrome, or drug-induced hypersensitivity was reasonably possible have been reported in Japan. Similar precautions have already been issued for other 5-aminosalicylic acid preparations. For these reasons, the MHLW/PMDA concluded that revision of Precautions was necessary in consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of Precautions.

Reference: Number of cases* and patient mortalities involving toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson syndrome), drug-induced hypersensitivity syndrome reported in Japan

<Toxic epidermal necrolysis (TEN)>

A total of 7 cases have been reported to date (including 2 cases for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities have been reported to date.

<Oculomucocutaneous syndrome (Stevens-Johnson syndrome)>

A total of 7 cases have been reported to date (including 1 case for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities have been reported to date.

<Drug-induced hypersensitivity syndrome>

A total of 17 cases have been reported to date (including 7 cases for which a causal relationship between the drug and event was reasonably possible).

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

*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

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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).