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

Preparations containing sulfamethoxazole sodium or sulfamethoxazole (OTC antibacterial ophthalmic solution)

August 27, 2024

Non-proprietary name

a. Preparations containing sulfamethoxazole sodium
b. Preparations containing sulfamethoxazole

Brand name (marketing authorization holder)

a. Rohto Antibacterial Eye Drops i (Rohto Pharmaceutical Co., Ltd.) and the other OTC drugs
b. Sante Medical Antibacterial (Santen Pharmaceutical Co., Ltd.) and the other OTC drugs

Japanese market launch

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Indications

Hordeolum, conjunctivitis (epidemic conjunctivitis), eye itching, blepharitis (erosion of eyelid)

Summary of revisions

a., b.

1. In the “When not to use the product” section, “This drug product should not be used in the following persons” section should be newly added and “Persons who have had an allergic symptom to this product or ingredients of this product” should be added.
2. In the Consultation section, “shock (anaphylaxis)” should be added.

Investigation results and background of the revision

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Cases involving anaphylaxis were evaluated. Cases for which a causal relationship of anaphylaxis to preparations containing sulfamethoxazole sodium or sulfamethoxazole 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 anaphylaxis reported in Japan

A total of 4 cases have been reported to date. (A causal relationship between the drug and event was reasonably possible for these cases.)

No patient mortalities have been reported 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).

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