Summary of Investigation Results

Triamcinolone acetonide (ophthalmic injection)

November 13, 2024

Non-proprietary name

Triamcinolone acetonide

Brand name (marketing authorization holder)

MaQaid Ophthalmic Injection 40 mg (Wakamoto Pharmaceutical Co., Ltd.)

Japanese market launch

December 2010

Indications

<Intravitreal injection>

•Visualization of the vitreous body during vitreous surgery

•Diabetic macular oedema

<Subtenon injection>

Alleviation of macular oedema associated with the following diseases

•Diabetic macular oedema

•Retinal vein occlusion

•Noninfective uveitis

Summary of revisions

1. “Eye disorders” should be added to the 11.1 Clinically Significant Adverse Reactions section in 11. ADVERSE REACTIONS for <Intravitreal injection: Visualization of the vitreous body during vitreous surgery>, and a precautionary statement regarding endophthalmitis should be added.
2. The following 2 items should be added for <Subtenon injection>.

1) A precautionary statement regarding infective scleritis should be added to the 8. IMPORTANT PRECAUTIONS section.
2) "Infective scleritis" should be added to the Eye disorders subsection in the 11.1 Clinically Significant Adverse Reactions section of 11. ADVERSE REACTIONS.

Investigation results and background of the revision

Cases involving endophthalmitis for <Intravitreal injection: Visualization of the vitreous body during vitreous surgery> and cases involving infective scleritis for <Subtenon injection> were evaluated. Cases for which a causal relationship of triamcinolone acetonide (ophthalmic injection) to endophthalmitis or infective scleritis 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 endophthalmitis† reported in Japan for <Intravitreal injection: Visualization of the vitreous body during vitreous surgery>

A total of 3 cases have been reported to date. (A causal relationship between the drug and the event was reasonably possible for these 3 cases, including 1 case in which this drug was not completely removed from the patient who did not comply with PRECAUTIONS.)
No patient mortalities have been reported to date.

Reference: Number of cases* and patient mortalities involving infective scleritis‡ reported in Japan for <Subtenon injection>

A total of 5 cases have been reported to date. (A causal relationship between the drug and the event was reasonably possible for these 5 cases, including 2 cases in which the drug was administered outside the approved indications.)
No patient mortalities have been reported to date.

*Cases collected in the PMDA's database for adverse drug reactions, etc. reports
†Cases retrieved under the following conditions
- •Cases with an adverse reaction name (PT) containing "endophthalmitis"
- •Cases in which this drug was used for the purpose of visualization of the vitreous body during vitreous surgery. Of note, cases with aseptic endophthalmitis caused by

administration (where the drug was retained in the vitreous body) of this drug were excluded.

‡Cases retrieved by the following conditions

•Among the cases retrieved by MedDRA ver.27.1 SOC “Infections and infestations,” those with scleritis occurring after administration of this drug.

•Cases in which this drug was administered by subtenon injection

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).