This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare. This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of PRECAUTIONS

Triamcinolone acetonide (ophthalmic injection)

November 13, 2024

Therapeutic category

Agents for ophthalmic use

Non-proprietary name

Triamcinolone acetonide (ophthalmic injection)

Safety measure PRECAUTIONS should be revised.

Revised language is underlined.

| Nevised language is underlined | |
|---|---|
| Current | Revision |
| 8. IMPORTANT PRECAUTIONS | 8. IMPORTANT PRECAUTIONS |
| <subtenon injection=""></subtenon> | <subtenon injection=""></subtenon> |
| (N/A) | Infective scleritis may occur. Patients should be closely monitored |
| | after administration of this drug. The patients must be instructed to |
| | immediately consult physicians if any abnormalities are observed. |
| 11. ADVERSE REACTIONS | 11. ADVERSE REACTIONS |
| 11.1 Clinically Significant Adverse Reactions | 11.1 Clinically Significant Adverse Reactions |
| (N/A) | <intravitreal body="" during="" injection:="" of="" p="" the="" visualization="" vitreous="" vitreous<=""></intravitreal> |
| | surgery> |
| | Eye disorders |
| | Endophthalmitis may occur. Surgical intervention may be needed. |
| <subtenon injection=""></subtenon> | <subtenon injection=""></subtenon> |
| Eye disorders | Eye disorders |
| Cataract, increased intraocular pressure, <u>or</u> glaucoma may occur. | Cataract, increased intraocular pressure, glaucoma, or infective |
| Surgical intervention may be needed. | scleritis may occur. Surgical intervention may be needed. |

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.