



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

Rebamipide

March 24, 2015

Non-proprietary name

Rebamipide (ophthalmic solution)

Safety measure

Precautions should be revised in the package insert.

In the Clinically significant adverse reactions subsection of the Adverse reactions section, the following texts should be added newly (underlined parts are revised):

Lacrimal duct obstruction and dacryocystitis:

Lacrimal duct obstruction and/or dacryocystitis may occur. Patients should be carefully monitored through ophthalmologic examination etc. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken. White matters may be observed in lacrimal passage of patients with lacrimal duct obstruction and/or dacryocystitis.

NOTE

- This drug is designated to prepare a Drug Guide for Patients.