



## Summary of investigation results

### Rebamipide

March 24, 2015

#### **Non-proprietary name**

Rebamipide (ophthalmic solution)

#### **Brand name (Marketing authorization holder)**

Mucosta Ophthalmic Suspension UD 2% (Otsuka Pharmaceutical Co., Ltd.)

#### **Indications**

Dry eyes

#### **Summary of revision**

The Clinically significant adverse reactions section should include ‘lacrimal duct obstruction and dacryocystitis.’

#### **Background of the revision and investigation results**

Cases of adverse events suggestive of lacrimal duct obstruction or dacryocystitis have been reported in patients treated with rebamipide ophthalmic solution in Japan. Following an investigation based on the opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

#### **The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan**

A total of 8 cases of adverse events suggestive of lacrimal duct obstruction or dacryocystitis have been reported (including 5 cases in which causality could not be ruled out). No fatalities have been reported.