



*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

## Eculizumab (genetical recombination)

February 8, 2019

### Non-proprietary name

Eculizumab (genetical recombination)

### Safety measure

Precautions should be revised in the package insert.

The language concerning the inhibition of thrombotic microangiopathy in patients with atypical hemolytic uremic syndrome in the Precautions for Indications section should be revised as follows (revised language is underlined):

This drug should be used in patients with atypical hemolytic uremic syndrome\* caused by complement dysregulation.

\*The 2015 Guidelines for the Management of Atypical Hemolytic Uremic Syndrome (aHUS) (The Japanese Society of Nephrology and the Japan Pediatric Society) should be referred to.

And the following language should be added thereto:

The safety and efficacy of this drug in patients with secondary thrombotic microangiopathy has not been established (no clinical experience.)