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*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

## Ciclosporin (oral and injectable dosage forms)

July 10, 2018

### **Non-proprietary name**

Ciclosporin (oral and injectable dosage forms)

### **Safety measure**

Precautions should be revised in the package insert.

“Pregnant women, women who may be pregnant, or breast-feeding women” should be deleted from the Contraindications section.

Language concerning pregnant women or women who may be pregnant in the Use during Pregnancy, Delivery or Breastfeeding section should be revised as follows (revised language is underlined):



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Pregnant women or women who may be pregnant should be administered this drug only if the potential therapeutic benefits are considered to outweigh the potential risks.

[Teratogenic effects, dystocia, and perinatal death have been reported in animal studies using rats. Placental transfer in humans has been reported. Premature birth cases and influence on the infants (low birth weight, congenital anomalies) have been reported in women who received this drug during pregnancy.]

- (References)
- Baxi, L.V., et al. :Am.J.Obstet.Gynecol. 1993;169(1):33
  - Burrows, D.A., et al. :Obstet.Gynecol. 1988;72(3):459
  - Lowenstein, B.R., et al. :Am.J.Obstet.Gynecol. 1988;158(3):589
  - Flechner, S.M., et al. :Am.J.Kidney Dis. 1985;5(1):60
  - Coscia, L.A., et al.
  - BestPract.Res.Clin.Obstet.Gynaecol. 2014;28(8):1174