



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

Tacrolimus hydrate (ophthalmic solution)

July 10, 2018

Non-proprietary name

Tacrolimus hydrate

Safety measure

Precautions should be revised in the package insert.

“Pregnant women or women who may be pregnant” 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):

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 and fetal toxicity have been reported as observed in animal studies [rabbits, orally administered.] Placental transfer in humans [orally administered] has been reported.)

(References) Saegusa, T. et al.:The Clinical Report 1992;26(3):969
Zheng,S.,et al.:Br.J.Clin.Pharmacol. 2013;76(6):988