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Revision of Precautions

Taclorimus hydrate (oral and injectable dosage forms)

July 10, 2018

Non-proprietary name

Tacrolimus hydrate (oral and injectable dosage forms)

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 etc.:
Pregnant women or women who may be pregnant <u>should be administered this drug only if the potential therapeutic benefits are considered to outweigh the potential risks.</u>
(Teratogenic effects and fetal toxicity have been reported in the reproductive toxicity studies using rabbits. <u>Placental transfer in humans has been reported. Premature birth and influence on the infants [low birth weight, congenital anomalies, hyperkalaemia, renal impairment] have been reported in women who received this drug during pregnancy)</u>

(References) Zheng,S., et al. :Br.J.Clin.Pharmacol. 2013;76(6):988
Coscia,L.A., et al. :Best Pract.Res.Clin.Obstet.Gynaecol. 2014; 28(8):1174

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