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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Mycophenolate Mofetil

March 23, 2016（March 29 revised）

Non-proprietary name

Mycophenolate Mofetil

Safety measure

Precautions should be revised in the package insert.

In the Warning section, the following text should be added (underlined parts are revised):

> This drug has demonstrated teratogenic effects in humans. Women of reproductive potential must undergo pregnancy testing before administration of this drug, and treatment can only be initiated after confirming negative test results. In addition, prior to initiating treatment up until 6 weeks after stopping treatment with this drug, patients must utilize reliable contraception methods and also be periodically checked by consultations and repeated pregnancy tests, etc. to ensure that no pregnancy occurs.

In the Relative Contraindications section, the following texts should be deleted:

> Women of reproductive potential

In the Important Precautions section regarding teratogenic effects, the following text should be revised (underlined parts are revised):

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This drug has teratogenic effects; therefore, women of reproductive potential must be made aware of the following cautionary points before use.

1. This drug has been reported to cause teratogenicity.
2. Pregnancy tests must be conducted prior to initiating treatment with this drug and test results must be negative.
3. Contraception must be utilized before, during and for 6 weeks after stopping treatment with this drug.
4. Patients should be periodically checked by consultations and repeated pregnancy tests, etc. to ensure that no pregnancy occurs during the administration of this drug. If pregnancy is suspected, the patient should immediately contact the doctor in charge.

In the Use in Pregnant, Parturient and Nursing Women section regarding pregnant women or women of reproductive potential, the following text should be revised (underlined parts are revised):

This drug should not be administered to pregnant women or women suspected of being pregnant. [Teratogenicity including those of the ears (external auditory canal atresia, microtia, etc.), eyes (coloboma, microphthalmos, etc.), face (hypertelorism of the orbits, micrognathia, etc.), fingers (syndactyly, polydactyly, brachydactyly, etc.), heart (atrial and ventricular septal defect, etc.), esophagus (esophageal atresia, etc.), and nervous system (spina bifida, etc.) have been reported among patients taking this drug during pregnancy. Abortions have been reported in 45 to 49% of pregnant women exposed to this drug. Furthermore, in teratology studies, exencephaly, gastroschisis, etc. in rats (at 6 mg/kg/day), and patent ductus arteriosus, thoracoschisis, gastroschisis, etc. in rabbits (at 90 mg/kg/day) have been reported.]

In the Use in Pregnant, Parturient and Nursing Women section regarding pregnant women or women of reproductive potential, the following texts should be deleted:

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As a general rule, this drug should not be administered to women of reproductive potential; however, if administration is absolutely necessary, the drug should only be administered if it is determined that treatment benefits outweigh the associated risks.

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