Drug Information Sheet("Kusuri-no-Shiori")

Internal
Revised: 03/2020

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name:Prograf Capsules 1mg [for transplantation]

Active ingredient: Tacrolimus hydrate
Dosage form:white capsule (length: 11.5 mm)
Print on wrapping:(Face)プログラフ 1mg, house-mark, f617, プログラフ 1,
(Back)1mg Prograf, 1mg プログラフ, プログラフ 1, Prograf 1, タクロリムス(Tacrolimus), house-mark, アステラス製薬

Effects of this medicine

This medicine inhibits the production of proteins called cytokines associated with organ transplant rejection, and thus suppresses refusal response.
It is usually used to prevent organ transplant rejection (kidney, liver, heart, lung, pancreas, small intestine, bone marrow) or graft-versus-host reaction (bone-marrow transplantation only).

Before using this medicine, be sure to tell your doctor and pharmacist

・If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines.
If you have: infections, renal disorder or liver disorder.
・If you are pregnant or breastfeeding.
・If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

・Your dosing schedule prescribed by your doctor is((to be written by a healthcare professional))
・For kidney transplantation: In general, take 0.15 mg/kg of tacrolimus at a time, twice a day from 2 days before transplantation. In the early stage after operation, take 0.15 mg/kg at a time twice a day. Subsequently, the dosage should be gradually decreased. The standard maintenance dose is 0.06 mg/kg at a time twice a day. The dosage may be adjusted according to the symptoms.
For liver transplantation: In general, take initially 0.15 mg/kg of tacrolimus at a time twice a day. Subsequently, the dosage should be gradually decreased. The standard maintenance dose is 0.10 mg/kg a day. The dosage may be adjusted according to the symptoms.
For heart transplantation: In general, take initially 0.03 to 0.15 mg/kg of tacrolimus at a time twice a day. When tacrolimus is used after development of organ rejection, take 0.075 to 0.15 mg/kg at a time twice a day. Subsequently, the dosage may be adjusted according to the symptoms. After stable condition is achieved, the dosage should be gradually decreased and maintained at the minimal effective dose.
For lung transplantation: In general, take initially 0.05 to 0.15 mg/kg of tacrolimus at a time twice a day. Subsequently, the dosage may be adjusted according to the symptoms. After stable condition is achieved, the dosage should be gradually decreased and maintained at the minimal effective dose.
For pancreas transplantation: In general, take initially 0.15 mg/kg of tacrolimus at a time twice a day. Subsequently, the dosage should be gradually decreased and maintained at the minimal effective dose.
For small intestine transplantation: In general, take initially 0.15 mg/kg of tacrolimus at a time twice a day. Subsequently, the dosage should be gradually decreased and maintained at the minimal effective dose.
For bone marrow transplantation: In general, take 0.06 mg/kg of tacrolimus at a time twice a day from 1 day before transplantation. In the early stage after transplantation, take 0.06 mg/kg at a time twice a day and the dosage should be gradually decreased. When used after the development of GVHD, take 0.15 mg/kg at a time twice a day. The dosage may be adjusted according to the symptoms.
This preparation contains 1 mg of tacrolimus in a capsule. In any case, strictly follow the instructions.
・If you miss a dose, take a dose as soon as possible. However, the next dose should be at least 5 hours apart. You should never take two doses at one time.
・If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
・Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

・Since you are likely to become infected, wash hands and gargle and regulate your daily life.
・Avoid taking grapefruit (juice) with this medicine, since it may intensify the therapeutic effects of this medicine.
・Avoid taking any food containing St. John's wort with this medicine, since it may diminish medicinal effects.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include renal disorder, elevation of blood pressure, tremor (shivering

of hands/fingers/feet), infections and diabetes mellitus. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, see your doctor immediately.

- ・decreased urinary output, general edema, thirst [acute renal disorder, nephrotic syndrome]
- ・palpitations, shortness of breath, chest distress, general edema, chest pain [heart failure, arrhythmia, myocardial infarction, angina pectoris, pericardial effusion, myocardial disorder]
- ・convulsion, consciousness disorder, speech difficulties [central nervous system disorders including reversible posterior leukoencephalopathy syndrome, hypertensive encephalopathy, progressive multifocal leukoencephalopathy]
- ・headache, temporary consciousness disorder, paralysis of limbs on one side [cerebrovascular disorder]
- ・respiratory distress, breathing difficulty [respiratory distress, acute respiratory distress syndrome]
- ・fever, general malaise, cold-like symptoms [infections]
- ・dry mouth, excessive fluid intake/urination, getting tired easily [diabetes mellitus or aggravation of diabetes mellitus, hyperglycemia]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- ・Keep out of reach of children. Store away from direct sunlight, heat and moisture.
- ・Discard the remainder. Do not store them. Ask the pharmacist or medical facility how to discard them.
- ・Do not receive vaccination without an approval of your doctor.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.

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Brand name:Prograf Capsules 1mg [for autoimmune disease]

Active ingredient: Tacrolimus hydrate

Dosage form:white capsule (length: 11.5 mm)

Print on wrapping:(Face)プログラフ 1mg, house-mark, f617, プログラフ 1, (Back) 1mg Prograf, 1mg プログラフ, プログラフ 1, Prograf 1, タクロリムス(Tacrolimus), house-mark, アステラス製薬

Effects of this medicine

This medicine acts on immune-related T cells and suppresses inflammation by inhibiting the production of cytokines associated with inflammation. It will improve the following symptoms: muscle weakness in myasthenia gravis; swelling, pain, and stiffness in rheumatoid arthritis; renal symptoms such as albuminuria in lupus nephritis; symptoms of refractory ulcerative colitis; and interstitial pneumonia associated with polymyositis/dermatomyositis.
It is usually used to treat myasthenia gravis, rheumatoid arthritis, lupus nephritis, ulcerative colitis, interstitial pneumonia associated with polymyositis/dermatomyositis.

Before using this medicine, be sure to tell your doctor and pharmacist

・If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines.
If you have: infections, rheumatoid arthritis-associated interstitial pneumonia, renal disorder or liver disorder.
・If you are pregnant or breastfeeding.
・If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

・Your dosing schedule prescribed by your doctor is((to be written by a healthcare professional))
・For myasthenia gravis, lupus nephritis: In general, for adults, take 3 mg of tacrolimus at a time once a day after supper.
For rheumatoid arthritis: In general, for adults, take 3 mg of tacrolimus at a time once a day after supper. In elderly patients, the dose starts with 1.5 mg, once a day after supper, and may be increased up to 3 mg once a day, according to the symptoms.
For ulcerative colitis: In general, for adults, take initially 0.025 mg/kg of tacrolimus at a time twice a day after meal in the morning/evening. For subsequent 2 weeks, the dosage may be adjusted according to the patient's blood concentration. The maximum daily dose is 0.3 mg/kg in principle.
For interstitial pneumonia associated with polymyositis/dermatomyositis: In general, for adults, take initially 0.0375 mg/kg of tacrolimus twice a day, after meal in the morning/evening. Subsequently, the dosage may be adjusted according to the patient's blood concentration. The maximum daily dose is 0.3 mg/kg.
This preparation contains 1 mg of tacrolimus in a capsule. In any case, strictly follow the instructions.
・If you miss a dose, follow the instructions below.
For myasthenia gravis, lupus nephritis, rheumatoid arthritis: Take the missed dose at the next dosing time (after supper).
For ulcerative colitis, interstitial pneumonia associated with polymyositis/dermatomyositis: Take a dose as soon as possible. However, the next dose should be at least 5 hours apart.
In any case, you should never take two doses at one time or change the dosing schedule.
・If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
・Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

・Since you are likely to become infected, wash hands and gargle and regulate your daily life.
・Avoid taking grapefruit (juice) with this medicine, since it may intensify the therapeutic effects of this medicine.
・Avoid taking any food containing St. John's wort with this medicine, since it may diminish medicinal effects.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include renal disorder, elevation of blood pressure, tremor (shivering of hands/fingers/feet), infections and diabetes mellitus. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, see your doctor immediately.

・decreased urinary output, general edema, thirst [acute renal disorder, nephrotic syndrome]
・palpitations, shortness of breath, chest distress, general edema, chest pain [heart failure, arrhythmia, myocardial

infarction, angina pectoris, pericardial effusion, myocardial disorder]

- convulsion, consciousness disorder, speech difficulties [central nervous system disorders including reversible posterior leukoencephalopathy syndrome, hypertensive encephalopathy, progressive multifocal leukoencephalopathy]
- headache, temporary consciousness disorder, paralysis of limbs on one side [cerebrovascular disorder]
- respiratory distress, breathing difficulty [respiratory distress, acute respiratory distress syndrome]
- fever, dry cough, respiratory distress [interstitial pneumonia (when being used for rheumatoid arthritis)]
- fever, general malaise, cold-like symptoms [infections]
- dry mouth, excessive fluid intake/urination, getting tired easily [diabetes mellitus or aggravation of diabetes mellitus, hyperglycemia]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- Keep out of reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. Ask the pharmacist or medical facility how to discard them.
- Do not receive vaccination without an approval of your doctor.

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For further information, talk to your doctor or pharmacist.