ACTORGAN

(Mycophenolate Sodium)

180mg & 360mg Tablets

ایکٹورگان

(مائکوفینولیٹ سوڈیم)

۱۸۰ ملی گرام ۳۶۰ ملی گرام

گولیاں

Composition:
Each enteric coated tablet contains:
Mycophenolate Sodium (USP) Eq. to
Mycophenolic acid 180mg
(Product complies USP Specs).

Composition:
Each enteric coated tablet contains:
Mycophenolate Sodium (USP) Eq. to
Mycophenolic acid 360mg
(Product complies USP Specs).

WARNING

Immunosuppression may lead to increased susceptibility to infection and possible development of lymphoma and other neoplasms. Only physicians experienced in immunosuppressive therapy and management of organ transplant recipients should use Actorgan (mycophenolic acid). Patients receiving Actorgan should be managed in facilities equipped and staffed with adequate laboratory and supportive medical resources. The physician responsible for maintenance therapy should have complete information requisite for the follow-up of the patient. Female users of childbearing potential must use contraception. Use of Actorgan during pregnancy is associated with increased risks of pregnancy loss and congenital malformation.

INDICATIONS

Actorgan is used to stop the body's immune system from rejecting a kidney transplant. It is used together with other medicines containing cyclosporine and corticosteroids.

WARNINGS AND PRECAUTIONS

- If you are allergic to mycophenolic acid, mycophenolate sodium, mycophenolate mofetil or any of the other ingredients of this medicine.
- If you are pregnant or planning to become pregnant or if you are breast-feeding.
- If you have or have ever had serious digestive problems, such as stomach ulcer.
- If you have a rare hereditary enzyme deficiency of hypoxanthine-guanine phosphoribosyl transferase (HGPRT) such as Lesch-Nyhan or Kelley-Seegmiller syndrome
- This medication lowers the skin's level of protection from the sun. This increases the risk of skin cancer.
- If you already had hepatitis B or C, Actorgan may increase the risk of these diseases re-appearing.

DRUG INTERACTIONS

- Other immunosuppressant medicines such as azathioprine or tacrolimus.
- Medicines used to treat high blood cholesterol levels such as cholestyramine.
- Activated charcoal used to treat digestive problems such as diarrhea, upset stomach, and gas.
- Antacids that contain magnesium and aluminum.
- Medicines used to treat viral infections such as acyclovir or ganciclovir.

You should also tell your doctor if you plan to have any vaccinations. You must not donate blood during treatment with Actorgan and for at least 6 weeks after

stopping treatment.

Interaction with food and drink
Actorgan can be taken with or without food. You need to choose whether to take your tablets with or without food and then take them in the same way each day. This is to make sure that the same amount of your medication is absorbed into your body each day.

Older people
Elderly people (age 65 years or older) can take ACTORGAN without any need to adjust the usual recommended dose.

Children and adolescents
The use of Actorgan in children and adolescents is not recommended due to lack of data.

PREGNANCY AND BREAST-FEEDING
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will talk to you about the risks in case of pregnancy and the alternatives you can take to prevent rejection of your transplant organ.

Pregnancy
Mycophenolate causes a very high frequency of miscarriage (50%) and of severe birth defects (23 - 27%) in the unborn baby. Birth defects which have been reported include anomalies of ears, of eyes, of face (cleft lip/palate), of development of fingers, of heart, esophagus (tube that connects the throat with the stomach), kidneys and nervous system (for example spina bifida (where the bones of the spine are not properly developed). Your baby may be affected by one or more of these.

Breast-feeding
Do not take Actorgan if you are breast-feeding. This is because small amounts of the medicine can pass into the mother's milk.

Driving and using machines
Actorgan has not been shown to affect your ability to drive or use machines.

DOSAGE
The recommended daily dose of Actorgan is 1440 mg. This is taken as 2 separate doses of 720 mg each.
Take your tablets in the morning and in the evening.
The first dose of 720 mg will be given within 72 hours after transplantation.
If you have severe kidney problems your daily dose should not be more than 1440 mg.

If you take more Actorgan than you should
If you take more Actorgan than you should, or if someone else has taken your tablets, talk to a doctor or go to a hospital straight away. Medical attention may be necessary. Take the tablets with you and show them to your doctor or to the hospital staff. If you have run out of tablets, take the empty packaging with you.

If you forget to take Actorgan
If you forget to take Actorgan, take it as soon as you remember unless it is almost time for your next dose. Then take your next dose at the usual time. Ask your doctor for advice. Do not take a double dose to make up for a forgotten dose.

If you stop taking Actorgan
Do not stop taking Actorgan unless your doctor tells you to. Stopping Actorgan may increase the chance of your body rejecting your kidney transplant.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

POSSIBLE SIDE EFFECTS
- Signs of infection including fever, chills, sweating, feeling tired, drowsy, or lack of energy.
- Such infections could affect various parts of your body, but the parts most commonly affected are the kidneys, bladder, upper and/or lower airways.
- Vomiting blood, black or bloody stools, stomach or intestinal ulcer.
- Swelling of your glands, development of a new skin growth or enlargement of an existing skin growth, or changes in an existing mole.
- Low level of white blood cells
- Low level of calcium in the blood (hypocalcaemia)
- Low level of potassium in the blood (hypokalemia)
- High level of uric acid in the blood (hyperuricemia)
- High blood pressure (hypertension)
- Anxiety
- Diarrhea
- Pain in joints (arthralgia)

PRESENTATION
Actorgan 180mg and 360mg are available in blister packs of 20's and 120.

STORAGE CONDITIONS AND INSTRUCTIONS
- Store below 30°C in a dry place, protect from light.
- To be dispensed on the prescription of a registered medical practitioner only.
- Keep out of the reach of children.

ہدایات:
- خوراک ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
- دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔
- صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔
- بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:
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