

MOFECON-GR (MYCOPHENOLIC ACID GASTRO-RESISTANT TABLETS)

Mycophenolic Acid (as Mycophenolate Sodium) (180, 360 mg)

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What Mofecon-GR is used for

Mofecon-GR belong to the class of drugs known as immunosuppressants. Immunosuppressants reduce your body's response to anything that it sees as "foreign" – which includes transplant organs.

How Mofecon-GR works

Mofecon-GR is used to prevent your body from rejecting a transplanted kidney. Mofecon-GR is used together with other medicines containing ciclosporin and corticosteroids.

Before you use Mofecon-GR

Mofecon-GR will only be prescribed for you by a doctor experienced in transplantation medicine. Follow your doctor's instructions carefully. They might differ from the general information contained in this leaflet.

- When you must not use it

Do not take Mofecon-GR:

- If you are allergic (hypersensitive) to mycophenolate mofetil, mycophenolic acid or any of the other ingredients in this medicine
- If you are a woman who could be pregnant and you have not provided a negative pregnancy test before your first prescription as mycophenolate causes birth defects and miscarriage.
- If you are pregnant or planning to become pregnant or think you may be pregnant

- If you are not using effective contraception
- If you are breast-feeding.

If any of the above apply to you, talk to your doctor or pharmacist before taking Mofecon-GR.

-Pregnancy and breast-feeding

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

- Plan to become pregnant.
 - Miss or think you have missed a period, or have unusual menstrual bleeding, or suspect you are pregnant.
 - Have sex without using an effective method of contraception.
- If you do become pregnant during the treatment with mycophenolate, you must inform your doctor immediately. However, keep taking mycophenolate until you see your doctor.

Contraception in women taking Mofecon-GR

If you are a woman who could become pregnant you must always use two effective methods of contraception with Mofecon-GR, which includes:

- Before you start taking Mofecon-GR
- During your entire treatment with Mofecon-GR
- For 6 weeks after you stop taking Mofecon-GR

See your doctor about the most suitable contraception for you. This will depend on your individual situation. Contact your doctor as soon as possible, if you think your contraception may not have been effective or if you have forgotten to take your contraceptive pill.

Contraception in men taking Mofecon-GR

You must always use condoms during treatment and for at least 90 days after you stop taking Mofecon-GR.

If you are planning to have a child, your doctor will talk to you about the risks and the alternative treatments you can take to prevent rejection of your transplant organ.

- Before you start to use it

Tell your doctor straight away before start using Mofecon-GR:

- If you have a sign of infection such as a fever or sore throat
- If you have any unexpected bruising or bleeding
- If you have ever had a problem with your digestive system such as a stomach ulcer
- If you are planning to become pregnant

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription.

In particular, you should talk to your doctor if you are taking any of the following:

- 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 diarrhoea, upset stomach, and gas.
- antacids that contain magnesium and aluminium.
- medicines used to treat viral infections such as aciclovir or ganciclovir.

How to use Mofecon-GR

Always follow your doctors instructions carefully. Do not take Mofecon-GR exceeding the recommended dose.

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- How much to use

- The recommended daily dose of Mofecon-GR is 1440 mg, taken as 2 separate doses of 720mg each.
- This means that taking 4 tablets of Mofecon-GR 180mg or 2 tablets of Mofecon-GR 360mg in the morning and 4 tablets of Mofecon-GR 180mg or 2 tablets of Mofecon-GR 360mg in the evening.
- The first dose of 720 mg will be given within 72 hours after transplantation.
- Your doctor will tell you exactly how many Mofecon tablets to take.

- How to take it

Swallow your tablets whole with a glass of water. Do not break or crush them.

- When to take it

Take Mofecon-GR as directed by your doctor.

- How long to use it

Consult your doctor regarding duration of treatment.

- If you forget to take it

If you forget to take Mofecon-GR at any time, take it as soon as you remember. Then continue to take it at the usual times. Do not take a double dose to make up for a missed dose.

- If you take too much (overdose)

If you take more Mofecon-GR than you should, talk to a doctor or go to a hospital straight away. Also do this if someone else accidentally takes your medicine. Take the medicine pack with you.

While you are using Mofecon-GR

- Things you must do

- Wear protective clothing which covers your head, neck, arms and legs and/or use a sunscreen with a high protection factor to limit the amount of sunlight and UV light you get. This is because Mofecon-

GR reduces your body's defenses and increases risk of skin cancer.

- If you are a woman who could become pregnant you must use an effective method of contraception (two forms of contraception are preferable) with Mofecon-GR. This includes: before you start taking Mofecon-GR, during your entire treatment with Mofecon-GR and for 6 weeks after you stop taking Mofecon-GR.

- Things you must not do

Do not stop taking Mofecon-GR unless your doctor tells you to. If you stop your treatment, you may increase the chance of rejection of your transplanted organ. If you have any further questions on the use of this product, ask your doctor or pharmacist.

- Things to be careful of

If you need to have a vaccine (a live vaccine) while taking Mofecon-GR, talk to your doctor or pharmacist first. Your doctor will have to advise you on what vaccines you can have.

You must not donate blood during treatment with Mofecon-GR and for at least 6 weeks after stopping treatment.

Men must not donate semen during treatment with Mofecon-GR and for at least 90 days after stopping treatment.

Side effects

Like all medicines, Mofecon-GR can cause side effects, although not everybody gets them. Talk to a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- you have a sign of infection such as a fever or sore throat
- you have any unexpected bruising or bleeding
- you have a rash, swelling of your face, lips, tongue or throat, with difficulty breathing - you may be having a serious allergic reaction to the medicine (such as anaphylaxis, angioedema)

Usual problems

Some of the more usual problems are diarrhoea, fewer white cells or red cells in your blood, infection and vomiting. Your doctor will do regular blood tests to check for any changes in:

- the number of your blood cells
- the amount in your blood of things like sugar, fat or cholesterol.

Children are more likely to cause these side effects.

Fighting infections

Mofecon-GR reduces your body's defenses. This is to stop you rejecting your transplant. As a result, your body will not be as good as normal at fighting infections. This means you may catch more infections than usual. This includes infections of the brain, skin, mouth, stomach and gut, lungs and urinary system.

Lymph and skin cancer

As can happen in patients taking this type of medicine (immune-suppressants), a very small number of Mofecon-GR patients have developed cancer of the lymphoid tissues and skin.

General unwanted effects

You may get general side effects affecting your body as a whole. These include serious allergic reactions (such as anaphylaxis, angioedema), fever, feeling very tired, difficulty sleeping, pains (such as stomach, chest, joint or muscle, pain on passing urine), headache, flu symptoms and swelling.

You are advised to consult your doctor or pharmacist for further information.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction monitoring by visiting the website npra.gov.my [Consumers-> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

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Storage and Disposal of Mofecon-GR

- Storage

Keep out of reach of children.
Store below 30°C. Protect from light and moisture.

- Disposal

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product description

- What it looks like

Mofecon-GR 180 is a lime green colored, enteric coated, round biconvex tablet, debossed with “C 1” on one side and plain on other side.

Mofecon-GR 360 is a pink to light pink colored, enteric coated, ovaloid biconvex tablet, debossed with “C 2” on one side and plain on other side.

- Ingredients

-Active ingredients

Mofecon-GR 180: Each tablet consists of Mycophenolic Acid 180 mg.

Mofecon-GR 360: Each tablet consists of Mycophenolic Acid 360 mg.

- MAL Number:

MALXXXXXXACZ

Manufacturer

Concord Biotech Limited
297-298/2p, Siyawada, Valthera,
Ahmedabad, Gujarat 382225, India.

Product Registration Holder

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