

MOFECON 500 (MYCOPHENOLATE MOFETIL 500MG TABLETS)

Mycophenolate Mofetil (500mg)

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What Mofecon is used for

Mofecon is indicated to prevent the body from rejecting a transplanted organ in patients receiving kidney, heart or liver transplants in combination with drugs like ciclosporin and corticosteroids.

Mofecon is used for treatment of kidney inflammation, lupus nephritis and it should be used together with other medicine known as corticosteroids.

How Mofecon works

Mofecon belongs to a drug class "immunosuppressant". It reduces immune response from your body.

Before you use Mofecon

- When you must not use it

Do not take Mofecon

- If you are allergic (hypersensitive) to mycophenolate mofetil, mycophenolic acid or any of the other ingredients listed at the end of this leaflet.
- If you are a woman who could be pregnant and not using effective contraception
- If you are pregnant or planning to become pregnant or think you may be pregnant
- If you are breast-feeding

If you are not sure, talk to your doctor or pharmacist before taking Mofecon.

- Before you start to use it

Tell your doctor straight away before start using Mofecon:

- If you are pregnant or planning to become pregnant
- If you are breast-feeding or plan to breast-feed
- If you are a sexually active man
- If you are allergic to any other medicines, foods, dyes or preservatives
- If you have any other health problems, especially the following:
 - a history of sun spots or skin cancers.
 - a history of low blood counts of neutrophils (a type of white blood cell).
 - a history of serious stomach or bowel problems (such as ulcers or bleeding).
 - kidney disease.
 - rare hereditary deficiency of certain enzymes, such as Lesch-Nyhan Syndrome and Kelley-Seemiller Syndrome.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including any that you have bought without a prescription from a pharmacy, supermarket or health food shop.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines before you start Mofecon:

- Azathioprine or other medicines which suppress your immune system - given after a transplant operation
- Aciclovir, ganciclovir, valaciclovir or valganciclovir - used to treat viral infections
- Antacids or proton pump inhibitors - used for acid problems in your stomach such as indigestion
- Cholestyramine - used to treat high cholesterol

- Norfloxacin plus metronidazole and amoxicillin plus clavulanic acid, combination antibiotics - used to treat infections
- Rifampicin and ciprofloxacin, medicines - used to treat infections
- Calcium-free phosphate binders (such as sevelamer) - used to treat high phosphate levels in the blood
- Isavuconazole - used to treat fungal infections
- Telmisartan - used to treat high blood pressure

How to use Mofecon

- How much to use

Take Mofecon exactly as your doctor has prescribed.

Your doctor will tell you how many tablets to take each day.

The dose to prevent organ rejection is usually 1 g to 1.5 g in the morning and 1 g to 1.5 g at night (2 g to 3 g per day) depending on which organ has been transplanted.

The dose to treat lupus nephritis is usually 1 g in the morning and 1 g at night (2 g per day).

- 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 as directed by your doctor before or after food.

- How long to take it

Consult your doctor regarding duration of treatment.

- If you forget to use it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember and then go back to taking it as you would normally.

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Do not double a dose to make up for one you have missed.

- If you use too much (overdose)

Immediately contact your doctor, or go to the Emergency Department at your nearest hospital, if you think you or anyone else may have taken too much Mofecon. Do this even if there are no signs of discomfort or poisoning.

While you are using Mofecon

- 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 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 reliable forms of contraception are preferable) with Mofecon. This includes: before you start taking Mofecon, during your entire treatment and for 6 weeks after you stop taking Mofecon.

- Things you must not do

Do not stop taking Mofecon 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.

You must not donate blood during treatment with Mofecon and for at least 6 weeks after stopping treatment. Men must not donate semen during treatment with Mofecon and for at least 90 days after stopping treatment.

- Things to be careful of

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

Be careful driving or operating machinery until you know how Mofecon affects you. Mofecon may have a moderate influence on the ability to drive and use machines. Please be cautious when driving or using machines if you experience somnolence, confusion, dizziness, tremor or hypotension during treatment with Mofecon.

Side effects

Like all medicines, Mofecon 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 if:

- 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)

Mofecon 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.

Patients who receive immunosuppressant medicines may also have a small increase in their risk of developing some types of cancer. You should discuss this with your doctor.

Tell your doctor if you notice any of the following:

- diarrhoea, constipation, nausea (feeling sick) or indigestion
- stomach, chest, back or other pain
- headache
- fluid in the legs or arms
- urinary infections.

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

Tell your doctor or pharmacist if you notice any of the following: fever, joint pain and muscle pain.

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

Storage and Disposal of Mofecon

- 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 500 (Mycophenolate Mofetil 500mg Tablets) is a lavender-colored, caplet-shaped, film coated tablet, debossed with "C4" on one side and plain on the other side.

- Ingredients

-Active ingredients

- Each tablet consists of 500mg mycophenolate mofetil.

-Inactive ingredients

- Microcrystalline Cellulose
- Croscarmellose Sodium
- Povidone
- Magnesium Stearate
- Opadry Purple 03B50110

- MAL Number:

MAL22066004ACZ

Manufacturer

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

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Mycophenolate Mofetil (500mg)

Product Registration Holder

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Date of revision

14/11/2022

Serial Number

NPRA (R2) 21/060