

Consumer Medicine Information

MYACCORD

Mycophenolate mofetil 250 mg capsules and 500 mg tablets

What is in this leaflet

- This leaflet answers some if not all of the common questions about MYACCORD capsules and tablets.
- It will not have all the available information.
- It does not take the place of talking to your doctor or pharmacist.
- Your doctor has weighed the risks of you taking MYACCORD against its benefits before prescribing it for you.
- If you have any concerns about taking this medicine do ask your doctor or pharmacist.
- Keep this leaflet with the medicine. You may need to read it again.

What is MYACCORD used for

- MYACCORD contains the active ingredient mycophenolate mofetil which belongs to a group of medicines called immunosuppressants. It is these immunosuppressants that are used to prevent rejection of transplanted organs, and work by stopping your immune system from reacting to the transplanted organ.
- MYACCORD may be used together with other medicines known as ciclosporin and corticosteroids.
- At times your doctor may have prescribed MYACCORD for some other purpose.
- If in doubt, do ask your doctor if you have any questions about MYACCORD.
- This medicine is available only with a doctor's prescription.

When you must not take it

- The medicine should not be taken if:
 1. the package is torn or shows signs of tampering

2. the expiry date printed on the pack has passed. The medicine may not work as well if you take it after the expiry date has passed.
3. you have had an allergic reaction to MYACCORD or any ingredients listed at the end of this leaflet.
Allergic reaction symptoms include swelling, itching, rash, breathing difficulties.

- Before you start to take MYACCORD do inform your doctor if:

1. you are pregnant or plan to become pregnant
It is not known whether MYACCORD is known to cause harmful effects to an unborn baby. However, birth defects have been reported in patients exposed to mycophenolate mofetil, in combination with other immunosuppressants, during pregnancy. Your doctor will discuss the risks and benefits to you and the unborn baby if there is a need to take MYACCORD when you are pregnant.

Women of childbearing potential should have a pregnancy test to show they are NOT pregnant one week before starting to take MYACCORD.

2. you are breastfeeding or plan to breastfeed
your doctor may advise you to either stop breast-feeding, or to stop taking MYACCORD as it is not known if MYACCORD passes into breast milk.
3. you have any other health problems, especially the following:
 - severe kidney disease
 - a history of serious stomach or bowel problems (such as ulcers or bleeding)
 - a history of skin cancers or sun spots
 - you have a rare disease such as Kelly-Seegmiller syndrome or Lesch-Nyhan.
4. you are allergic to any other medicines, foods, dyes or preservatives.

If you have not told your doctor about any of the above, you should do so before you start taking MYACCORD.

Taking other medicines

Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, healthfood shop or supermarket.

Some medicines could interfere with Myaccord. These medicines include:

- antacids - a class of medicines for indigestion or heartburn

- azathioprine (Azamun[®], Imuran[®], Thioprine[®]): These medications are used to suppress the immune system.
- tacrolimus (Prograf[®]): Another medication used to suppress the immune system.
- aciclovir (Acicvir[®], Lovir[®], Zovirax[®], Viraban[®], Zolaten[®]), valaciclovir, ganciclovir (Cymevene[®]), valganciclovir (Valcyte[®]): These medications are used to treat viral infections.
- cholestyramine (Questran Light[®]): This medication is used to treat high blood cholesterol levels.
- Rifampicin (Rifadin[®], Rifinah[®]), ciprofloxacin (Cifran[®], Ciproxin[®], Cipflox[®]), amoxicillin plus clavulanic acid (Augmentin[®]), norfloxacin plus metronidazole. These are medicines used to treat infections.
- calcium-free phosphate binders (sevelamer): These medications are used to treat high blood phosphate levels.
- vaccinations - as they may not be as effective as normal. These are medicines that work by causing your body to produce its own protection against an infectious disease. Vaccination with live vaccines should be avoided.

These medicines may either be affected by MYACCORD or affect its action. You may need to alter the dosage of the medicine, or you may be required to change the medicine. Your doctor will advise you accordingly.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking MYACCORD.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How does one take MYACCORD

You are advised to follow all the directions given to you by your doctor or pharmacist very carefully. The doctor or pharmacist's advice may differ from the information in this leaflet.

How much to take

MYACCORD is to be taken exactly as your doctor has prescribed.

Your doctor will tell you how much MYACCORD to take each day.

The normal adult dose to prevent rejection is usually 2 g or 3 g per day, depending on which organ has been transplanted. This should be taken as 1g or 1.5 g in the morning, and another 1 g or 1.5 g at night.

The normal dose for children and adolescents (aged 3 months to 18 years) to prevent rejection of a kidney transplant depends on their body surface area. Your doctor will determine the daily dose up to a usual maximum of 2 g per day.

Your doctor may adjust your dose depending on your response.

How to take MYACCORD

Capsules and tablets should be swallowed whole with a glass of water.

If a tablet is crushed or capsules breaks, using soap and water, wash off the powder thoroughly. If powder enters your eyes, use water to rinse.

When to take it

It is best to take doses approximately 12 hours apart. Your dose can be taken with or without food.

Taking your medicine at the same time each day will have the best effect. It will also help you to remember when to take MYACCORD.

How long to take MYACCORD

MYACCORD should be taken every day. It is important to keep taking the medication to ensure your transplanted organ keeps working properly. It should be taken until the doctor tells you to stop.

If you forget to take 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.

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

If in doubt do ask your doctor or pharmacist. They can also help with hints if you have trouble remembering your dose.

Overdosage:

Immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice or go to your nearest Accident and Emergency centre if you think that you or anyone else may have taken too much MYACCORD. Do so even if there are no signs of poisoning or discomfort.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking MYACCORD you must

- Tell all doctors, dentists and pharmacists who are treating you that you are taking MYACCORD.
- Inform your doctor if you become pregnant while taking MYACCORD. It is important to use very effective contraceptive measures four weeks prior to taking MYACCORD, while you are taking MYACCORD and for six weeks after you stop taking MYACCORD. It is recommended that

two reliable forms of contraception be used at the same time if you are sexually active.

Tell your doctor or go to your nearest Accident and Emergency centre immediately if you think you may have an infection (signs may include fever, chills, local inflammation, sore throat or ulcers in the mouth, but there could be other symptoms), any evidence of unexpected bruising or any unexpected bleeding. As these are serious side effects while taking MYACCORD and you may need urgent medical attention.

MYACCORD reduces your body's own defence mechanisms to stop you rejecting your transplanted organ. Your body will not be as effective at fighting infection as it normally is. People taking MYACCORD often develop more infections than they normally would.

When outdoors, wear protective clothing and a broad-spectrum sunscreen with a high protection factor.

Medicines such as MYACCORD that prevent rejection of transplants, can cause a small increase in the risk of getting cancer, skin cancers in particular. You should discuss this with your doctor if it concerns you.

Tell your doctor if for any reason you have not taken the medicine as prescribed. Your doctor may otherwise think the medication was not effective and change the treatment prescribed unnecessarily.

If you feel your medicine is not helping your condition kindly discuss the same with your doctor.

Ensure you keep all of your appointments with your doctor so that your progress can be monitored. Your doctor may require you to give regular blood tests.

Things you must not do

- Do not give your MYACCORD medication to anyone else even if they have the same condition as you.
- Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting with a pharmacist.
- Do not stop taking MYACCORD or change the dose without first checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.
- Do not use MYACCORD to treat other conditions unless your doctor says to.

Things to be careful of

Until you know how MYACCORD affects you, be careful driving or operating machinery.

As with many other medicines used to prevent rejection of transplanted organs, MYACCORD may cause drowsiness, dizziness, or light-headedness in some people. Make sure you know how you react to MYACCORD before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy, drowsy or light-headed.

Side effects

If you do not feel well while taking MYACCORD, tell your doctor or pharmacist as soon as possible.

MYACCORD helps most people who have transplants but it could have some unwanted side effects. All medicines can have side effects. Sometimes the side effects are serious, most of the time they are not. Some of the side effects may require medical treatment.

If you are over 65 years of age you may have an increased chance of getting side effects.

Patients receiving immunosuppressant medicines may have a small increased risk of developing some types of cancers. This should be discussed with your doctor.

Ask your doctor or pharmacist to answer any questions you may have.

Inform your doctor if you notice any of the following and they concern you (These are the more common, mild, side effects of taking MYACCORD.):

- dizziness or shaking
- diarrhoea, constipation, nausea (feeling sick) or indigestion
- acne
- hair loss or itchy skin
- headache
- inability to sleep (insomnia)

Inform your doctor as soon as possible if you notice any of the following (These may be serious side effects and you may require medical treatment):

- fluid (swelling) in the legs, arms or face
- anxiety or depression
- cold sores
- signs of anaemia such as excessive tiredness, dizziness or looking pale
- stomach, back, muscle or other pain
- skin changes, especially changes in moles or freckles.

Inform your doctor immediately, or go to your nearest Accident and Emergency centre if you notice any of the following (These are serious

side effects and you may need urgent medical attention. Serious side effects are rare):

- any signs of infection such as fever, inflammation, sweating, chills or 'flu-like' symptoms
- vomiting
- clumsiness
- unexplained bleeding
- urinary infection or blood in your urine
- irregular heartbeat or chest pain
- changes in vision or speech
- weakness

This is not a complete list of all possible side effects. Others may occur in some individuals and there may also be some side effects that are not yet known. Tell your doctor or pharmacist if you notice anything else, that is not on the list, that is making you feel unwell.

Do ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking MYACCORD

Storage

Keep your capsules or tablets in the blister pack until it is time to take the next dosage.

Do not take the capsules and tablets out of the blister pack as they may not keep well.

Keep MYACCORD capsules away from moisture and keep the tablets in the carton where they are protected from light.

Light may cause the tablets to fade.

The medication should be stored in a cool dry place where the temperature stays below 25 °C.

Do not store them, or any other medicine, near a sink or in a bathroom.

Do not leave MYACCORD on windowsills or in the car.

Some medications can be destroyed by heat and dampness.

Keep MYACCORD out of reach of young children.

A good place to store medicines, is a locked cupboard at least one-and-a-half meters above the ground.

Disposal

If your doctor advises you to stop taking MYACCORD, or if the products have passed their expiry date, ask your pharmacist what to do with any remaining medicine.

Product description

What MYACCORD looks like

MYACCORD capsules are light blue/peach coloured, hard gelatin capsules with two bar lines on the cap and body containing white to off white powder. They come in packs of 30's, 90's and 100's.

MYACCORD tablets are purple coloured and capsule-shaped, biconvex film coated debossed with "ÄHI" engraved on one side and "500" on the other. They come in packs of 50's and 100's.

Ingredients

Active ingredient - mycophenolate mofetil

- MYACCORD capsules contain 250 mg of mycophenolate mofetil and tablets contain 500 mg of mycophenolate mofetil.

Inactive ingredients –

- Capsules: cellulose microcrystalline (Avicel PH 101), hydroxyl propyl cellulose, povidone K-90, croscarmellose sodium, talc, magnesium stearate and purified water. The capsule shells contain gelatin, FD & C blue, iron oxide yellow, iron oxide red, titanium dioxide, sodium lauryl sulphate and purified water. The printing ink contains black iron oxide, potassium hydroxide, shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonia solution and purified water.
- Tablets: microcrystalline cellulose, croscarmellose sodium, povidone, magnesium stearate, hydroxypropyl cellulose, talc, opadry 03B50110 purple and purified water.

MYACCORD capsules and tablets are gluten and lactose free.

Distributor

MYACCORD is distributed by:

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