

MYNOTIL FILM COATED TABLETS

Mycophenolate Mofetil (250mg, 500mg)

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What Mynotil is used for

Mynotil is used to prevent your body from rejecting a transplanted organ (kidney, heart or liver) and it should be used together with other medicines known as ciclosporin and corticosteroids.

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

Ask your doctor if you have any questions about why Mynotil has been prescribed for you. Your doctor may have prescribed Mynotil for another reason.

This medicine is available only with a doctor's prescription.

How Mynotil works

Mynotil contains mycophenolate mofetil. This belongs to a group of medicines called "immunosuppressants".

Immunosuppressants are used to prevent the rejection of a transplanted organ and work by stopping your immune system from reacting to the transplanted organ.

Before you use Mynotil

- **When you must not use it**

Do not take Mynotil if:

1. **You have had an allergy to:**
 - Mynotil or any ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching, hives on the skin

2. You are pregnant

- Mynotil is harmful to an unborn baby when taken by a pregnant woman.
- There have been cases of miscarriage and severe birth defects reported when patients took Mynotil during pregnancy.
- You must tell your doctor if you are pregnant or plan to become pregnant.

3. You are breastfeeding

- Mynotil may pass into human breast milk and could cause serious side effects in your baby if you breastfeed.

4. You are a woman who could become pregnant and you are not using two reliable forms of contraception

- You must use two reliable forms of contraception at the same time before beginning Mynotil therapy, during therapy and for at least six weeks after stopping Mynotil, unless you are not sexually active.

5. The package is torn or shows signs of tampering

6. The expiry date (EXP) printed on the pack has passed

- If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should start taking this medicine, talk to your doctor.

- **Before you start to use it**

Tell your doctor if:

1. You are pregnant or plan to become pregnant

- If you are a woman of child bearing potential, you must have two negative pregnancy tests 8- 10 days apart just prior to starting treatment with Mynotil.
- Repeat pregnancy tests will be performed during routine follow-up visits with your doctor.

2. You are breast-feeding or plan to breast-feed

3. You are a sexually active man

- You are recommended to use condoms during treatment and for 90 days after stopping treatment, even if you have had a vasectomy.
- Your female partner(s) are recommended to use reliable contraception while you are being treated with Mynotil and for 90 days after you have stopped receiving Mynotil.
- You should not donate semen while you are being treated with Mynotil and for 90 days after you have stopped receiving Mynotil.

4. You should not donate blood while you are being treated with Mynotil and for at least 6 weeks after you stop receiving Mynotil.

5. 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 ulceration or bleeding).
- Kidney disease.
- Rare diseases due to a deficiency of the HGPRT enzyme such as Lesch-Nyhan or Kelley-Seegmiller Syndrome.

6. You have allergies to any other medicines, foods, preservatives

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or dyes.

If you have not told your doctor about any of the above, tell him/her before you start taking Mynotil.

- **Taking other medicines**

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

Some medicines and Mynotil may interfere with each other. These include:

- azathioprine, tacrolimus and sirolimus, medicines used to suppress the immune system which can be used to prevent organ rejection after a transplant
- aciclovir, ganciclovir, valaciclovir or valganciclovir, medicines used to treat viral infections
- isavuconazole, a medicine used to treat fungal infections
- cholestyramine, a medicine used to treat high cholesterol
- ciprofloxacin, amoxicillin plus clavulanic acid, norfloxacin plus metronidazole and rifampicin, medicines used to treat infections
- certain vaccines (especially live vaccines), medicines that work by causing your body to produce its own protection against an infectious disease
- proton-pump inhibitors, medicines used to treat indigestion and stomach ulcers such as lansoprazole and pantoprazole
- calcium-free phosphate binders (such as sevelamer), medicines used to treat high phosphate levels in the blood
- antacids, medicines used to treat heartburn and indigestion
- telmisartan, medicine used to lower blood pressure
- probenecid, medicine used to treat gout

These medicines may be affected by Mynotil, or may affect how well

it works. You may need to use different amounts of your medicine, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Mynotil.

How to use Mynotil

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the packet ask your doctor or pharmacist for help.

- **How much to use**

Take Mynotil exactly as your doctor has prescribed.

Your doctor will tell you how many Mynotil 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).

Your doctor may adjust your dose depending on your response.

- **How to take it**

Swallow the tablets whole with a glass of water.

Patients should also avoid inhalation or contact of the skin or mucous membranes with the powder contained in Mynotil. If such contact occurs, wash thoroughly with soap and water; rinse eyes with plain water.

Do not crush tablets.

- **When to use it**

It is best to take doses of Mynotil tablets approximately 12 hours apart.

Take your medicine at about the same time each day.

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

- **How long to use it**

Mynotil should be taken every day. It is important to keep taking Mynotil to ensure your new transplant keeps working properly.

Continue taking Mynotil for as long as your doctor tells you.

- **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.

Do not take a double dose to make up for the dose that you missed.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

- **If you use too much (overdose)**

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

You may need urgent medical attention.

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

While you are using it

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- Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Mynotil.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking Mynotil.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.
It may affect other medicines used during surgery.

Tell your doctor if you become pregnant while taking Mynotil.

If you are a woman of child bearing potential, you must use two reliable forms of contraception at the same time before beginning Mynotil therapy, during therapy and for at least six weeks after stopping Mynotil, unless you are not sexually active.

If you are a sexually active male, you are recommended to use condoms during treatment and for 90 days after stopping treatment, even if you have had a vasectomy.

Your female partner(s) are recommended to use reliable contraception while you are being treated with Mynotil and for 90 days after you have stopped receiving Mynotil.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel your medicine is not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Your doctor will need to give you

regular blood tests.

Wear protective clothing and broad-spectrum sunscreen when outdoors.

Medicines that prevent rejection of transplants can increase the risk of skin cancers.

- Things you must not do

Do not stop taking Mynotil or change the dose without first checking with your doctor.

Do not use Mynotil to treat other complaints unless your doctor tells you to.

Do not give your medicine to anyone else even if they have the same condition as you.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not crush Mynotil tablets.

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting with a pharmacist.

- Things to be careful of

Be careful driving or operating machinery until you know how Mynotil affects you or if you experience somnolence, confusion, dizziness, tremor or hypotension.

Mynotil may affect your ability to drive a car or operate machinery

Side effects

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

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Mynotil.

This medicine helps most people who have organ transplants, but may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

To stop you rejecting your organ, transplant medications reduce your body's own defense mechanisms. This means your body will not be as good at fighting infection. People taking Mynotil therefore develop 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.

If you are over 65 years of age, you may have an increased chance of getting side effects occurring due to immunosuppression.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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

Tell your doctor if you notice any of the following and they worry you:

- diarrhoea, constipation, nausea (feeling sick), vomiting or indigestion
- stomach, chest or back pain
- headache
- urinary infections

The above list includes the more common side effects of Mynotil.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- signs of other infections, e.g. fevers, chills, sore throat, ulcers of the mouth, abdominal pain or bloody stools
- unexpected bruising or bleeding
- signs of anaemia such as excessive tiredness, dizziness or looking pale
- swelling of the hands, ankles or feet, lymph nodes
- hypersensitivity
- breathing difficulties, pain in the

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chest, chronic cough with blood

The above list includes serious side effects. You may need urgent medical attention. Serious side effects are rare.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

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) or Vaccines (AEFI)].

Storage and Disposal of Mynotil

Storage

- Keep this medicine out of the sight and reach of children.
- Store below 30°C.
- Store in original container to protect from light and moisture.
- Do not take this medicine after the expiry date, which is stated on the pack.

Disposal

If you have any unwanted tablets do not put them in wastewater or household rubbish. Ask your pharmacist how to dispose of tablets you do not need.

This will help to protect the environment.

Product Description

What it looks like

Mynotil 250 mg Film Coated Tablets - Lavender-colored, oval-shaped tablets debossed with "250" on one side and "M" on the other side.

Mynotil 500 mg Film Coated

Tablets - Lavender-colored, capsule-shaped tablets debossed with "500" on one side and "M" on the other side.

Ingredients

- Active ingredients
The active substance of Mynotil 250 mg Film Coated Tablets is 250 mg Mycophenolate Mofetil.

The active substance of Mynotil 500 mg Film Coated Tablets is 500 mg Mycophenolate Mofetil.

- Inactive ingredients
Tablet core:
 - Microcrystalline Cellulose
 - Povidone
 - Croscarmellose Sodium
 - Magnesium Stearate

Film coat:

Mynotil 250 mg Film Coated Tablets and Mynotil 500 mg Film Coated Tablets: Opadry Complete Film Coating System Y-5R-10272-A Lavender

MAL number(s):

Mynotil 250 mg Film Coated Tablets: MALXXXXXXXX

Mynotil 500 mg Film Coated Tablets: MALXXXXXXXX

Manufacturer

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Product Registration Holder

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