Package leaflet: Information for the user

Myfenax 500mg film-coated tablets
mycophenolate mofetil

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Myfenax is and what it is used for

Myfenax is a medicine that is used to suppress immune activity.

The active substance in this medicine is called mycophenolate mofetil.

Myfenax is used to prevent your body rejecting a transplanted kidney, heart or liver. It is used in combination with other medicines with a similar function (i.e. ciclosporin and corticosteroids).

2. What you need to know before you take Myfenax

WARNING
Mycophenolate causes birth defects and miscarriage. If you are a woman who could become pregnant, you must provide a negative pregnancy test before starting treatment and must follow the contraception advice given to you by your doctor.
Your doctor will speak to you and give you written information, particularly on the effects of mycophenolate on unborn babies. Read the information carefully and follow the instructions.
If you do not fully understand these instructions, please ask your doctor to explain them again before you take mycophenolate. See also further information in this section under "Warnings and precautions" and "Pregnancy, contraception and breast-feeding".

Do not take Myfenax,
- if you are allergic to mycophenolate mofetil, mycophenolic acid or any of the other ingredients of this medicine (listed in section 6).
- 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 (see Pregnancy, contraception and breast-feeding).
- if you are breast-feeding.

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Myfenax.

Warnings and precautions
Talk to your doctor or pharmacist before starting treatment with Myfenax.
- if you experience any evidence of infection (e.g. fever, sore throat), unexpected bruising and/or bleeding.
- if you have or ever have had any problems with your digestive system, e.g. stomach ulcers.
- if you are planning to become pregnant, or if you get pregnant while you or your partner are taking Myfenax.

Myfenax reduces your body's defence mechanism. Because of this, there is an increased risk of skin cancer. Therefore you should limit your exposure to sunlight and ultraviolet (UV) light by wearing appropriate protective clothing and using a sunscreen with a high protection factor.

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

Children and adolescents
Myfenax is used in children and adolescents (aged 2 to 18) to prevent a body rejecting a transplanted kidney.
Myfenax should not be used in children and adolescents (aged 2 to 18) for heart or liver transplantation.
Myfenax should not be used at all in children under 2 years old.

Other medicines and Myfenax
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you answer yes to any of the following questions talk to your doctor before you start to take Myfenax:
- Are you taking any medicines containing:
  - azathioprine or other immunosuppressive agents (which are sometimes given to patients after a transplant operation),
  - cholestyramine (used to treat patients with high blood cholesterol),
  - rifampicin (antibiotic),
  - antacids or proton pump inhibitors (used for acid problem in your stomach such as indigestion),
  - phosphate binders (used in patients with chronic kidney failure to reduce the absorption of phosphate),
  - antibiotics (used to treat bacterial infections),
  - isavuconazole (used to treat fungal infections),
  - telmisartan (used to treat high blood pressure)
  - or any other medicines (including those you can buy without a prescription) that your doctor does not know about?
- Do you need to receive vaccines (live vaccines)? Your doctor will have to advise you what is indicated for you.

Pregnancy, contraception and breast-feeding

Contraception in women taking Myfenax
If you are a woman who could become pregnant you must use an effective method of contraception with Myfenax. This includes:
- Before you start taking Myfenax
- During your entire treatment with Myfenax
- For 6 weeks after you stop taking Myfenax.

Talk to your doctor about the most suitable contraception for you. This will depend on your individual situation. Two forms of contraception are preferable as this will reduce the risk of unintended pregnancy. **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.**

You are a woman who is not capable of becoming pregnant if any of the following applies to you:
- You are post-menopausal, i.e. at least 50 years old and your last period was more than a year ago (if your periods have stopped because you have treatment for cancer, then there is still a chance you could become pregnant).
- Your fallopian tubes and both ovaries have been removed by surgery (bilateral salpingo-oophorectomy).
- Your womb (uterus) has been removed by surgery (hysterectomy).
- Your ovaries no longer work (premature ovarian failure, which has been confirmed by a specialist gynaecologist).
- You were born with one of the following rare conditions that make pregnancy impossible: the XY genotype, Turner`s syndrome or uterine agenesis.
- You are a child or teenager who has not started having periods.

Contraception in men taking Myfenax
The available evidence does not indicate an increased risk of malformations or miscarriage if the father takes mycophenolate. However, a risk cannot be completely excluded. As a precaution you or your female partner are recommended to use reliable contraception during treatment and for 90 days after you stop taking Myfenax.

If you are planning to have a child, talk to your doctor about the potential risks and alternative therapies.

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 if:
- You plan to become pregnant.
- You miss or think you have missed a period, or you have unusual menstrual bleeding, or suspect you are pregnant.
- You 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 Myfenax until you see him or her.

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, oesophagus (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.
If you are a woman who could become pregnant, you must provide a negative pregnancy test before starting treatment and must follow the contraception advice given to you by your doctor. Your doctor may request more than one test to ensure you are not pregnant before starting treatment.

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

Driving and using machines
Myfenax has a moderate influence on your ability to drive or use any tools or machines. If you feel drowsy, numb or confused, talk to your doctor or nurse and do not drive or use any tools or machines until you feel better.

Myfenax contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Myfenax

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your treatment is started and monitored by a doctor who is specialised in transplants.

The usual way to take Myfenax is as follows:

Kidney Transplant

Adults
The first dose will be given within 72 hours after the transplant operation. The recommended daily dose is 4 tablets (2 g of the active ingredient) taken as 2 separate doses. This means taking 2 tablets in the morning then 2 tablets in the evening.

Children and adolescents (aged 2 to 18)
The dose given will vary depending on the size of the child. Your doctor will decide the most appropriate dose based on body surface area (height and weight). The recommended dose is 600 mg/m^2 taken twice a day.

Heart Transplant

Adults
The first dose will be given within 5 days following the transplant operation. The recommended daily dose is 6 tablets (3 g of the active ingredient) taken as 2 separate doses. This means taking 3 tablets in the morning then 3 tablets in the evening.

Children
There is no information for the use of Myfenax in children with a heart transplant.

Liver Transplant

Adults
The first dose of oral Myfenax will be given to you at least 4 days after the transplant operation and when you are able to swallow oral medicines. The recommended daily dose is 6 tablets (3 g of the active ingredient) taken as 2 separate doses. This means taking 3 tablets in the morning then 3 tablets in the evening.

Children
There is no information for the use of Myfenax in children with a liver transplant.

Method and route of administration
Swallow your tablets whole with a glass of water. You can take them with or without food. Do not break or crush them.

Treatment will continue for you as long as you need immunosuppression to prevent your body from rejecting your transplanted organ.

If you take more Myfenax than you should
It is important not to take too many tablets. Contact your nearest hospital Accident and Emergency department or a doctor for advice if you have swallowed more tablets than you have been told to take or if you think a child has swallowed any.

If you forget to take Myfenax
If you forget to take your medicine 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 forgotten dose.

If you stop taking Myfenax
Do not stop taking Myfenax because you feel better. It is important to take the medicine for as long as the doctor has told you to. Stopping your treatment with Myfenax may increase the chance of rejection of your transplanted organ. Do not stop taking your medicine unless your doctor tells you to.

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

4. Possible side effects

Like all medicines, this medicine 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).
- you have black or bloody stool or if you vomit blood or dark particles that look like coffee grounds. These may be signs of bleeding in the stomach or intestines.

The frequency of certain side effects is dependent on the transplanted organ, i.e. some side effects can occur more or less often depending on whether this medicinal product is being taken to prevent your body from rejecting a transplanted heart or a transplanted kidney. For the sake of clarity each side effect is always listed under its highest frequency.

Other side effects

Very common (may affect more than 1 in 10 people)
- bacterial, viral and/or fungal infections
- serious infection which may affect the whole body
- decrease in the number of white blood cells, platelets or red blood cells, which can result in increased risk of infections, bruising, bleeding, breathlessness and weakness
- bleeding underneath the skin
- increase in the number of white blood cells
- too much acid in the body
- high level of cholesterol and/or lipids in the blood
- high level of sugar in the blood
- high level of potassium in the blood, low level of potassium, magnesium, calcium and/or phosphate in the blood
- high level of uric acid in the blood, gout
- feeling restless, abnormalities of thought, perception and levels of awareness, depression, feeling anxious, difficulty in sleeping
- increased tension of the muscles, shaking, sleepiness, feeling dizzy, headache, tingling, pricking or numbness
- faster heart beat
- low/high blood pressure, widening of blood vessels
- accumulation of fluid in the lung, shortness of breath, cough
- bloated belly
- vomiting, stomach pain, diarrhoea, feeling sick

- constipation, indigestion, wind (flatulence)
- decreased appetite
- changes in different laboratory parameters
- inflammation of the liver, yellowing of the skin and whites of the eyes
- growth of the skin, rash, acne
- muscle weakness
- joint pain
- kidney problems
- blood in the urine
- fever, feeling of coldness, pain, feeling weak and feeble
- fluid retention in the body
- part of an internal organ or tissue bulging through a weak spot in the abdominal muscles

Common (may affect up to 1 in 10 people)
- skin cancer, non-cancerous growth of the skin
- abnormal and excessive growth of tissue
- decrease in the number of all blood cells
- benign enlargement of the lymph nodes, inflammatory changes of the skin (pseudolymphoma)
- decreased weight
- abnormal thinking
- fit
- distortion of the sense of taste
- blood clot that forms within a vein
- inflammation of the tissue that lines the inner wall of the abdomen and covers most of the abdominal organs
- bowel blockage
- inflammation of the colon which causes abdominal pain or diarrhoea (sometimes caused by cytomegalovirus), ulcer of the mouth and/or stomach and/or duodenum, inflammation of the stomach, oesophagus and/or mouth and lips
- belching
- hair loss
- feeling unwell
- overgrowth of the gum tissue
- inflammation of the pancreas, which causes severe pain in the abdomen and back

Uncommon (may affect up to 1 in 100 people)
- protozoal infections
- proliferation of the lymphatic tissue, including malignant tumours
- insufficient production of red blood cells
- serious diseases of the bone marrow
- accumulation of lymphatic fluid within the body
- shortness of breath, cough, which can be due to bronchiectasis (a condition in which the lung airways are abnormally dilated) or pulmonary fibrosis (scarring of the lung). Talk to your doctor if you develop a persistent cough or breathlessness.
- decrease in the amount of antibodies in the blood
- severe reduction in the number of certain white blood cells (possible symptoms are fever, sore throat, frequent infections) (agranulocytosis)

Not known (frequency cannot be estimated from the available data)
- alterations of the inner wall of the small intestine (intestinal villous atrophy)
- serious inflammation of the membrane that covers the brain and spinal cord
- serious inflammation of the heart and its valves
- bacterial infections usually resulting in a serious lung disorder (tuberculosis, atypical mycobacterial infection)

- serious disease of the kidney (BK virus associated nephropathy)
- serious disease of the central nervous system (JC virus associated progressive multifocal leucoencephalopathy)
- decrease in the number of certain white blood cells (neutropenia)
- change of the shape of certain white blood cells

Do not stop taking your medicine unless you have discussed this with your doctor first.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Myfenax

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Myfenax contains

- The active substance is mycophenolate mofetil.
  Each tablet contains 500mg of mycophenolate mofetil.
- The other ingredients are:
  Tablet core
  Microcrystalline cellulose
  Povidone K-30
  Magnesium stearate
  Croscarmellose sodium
  Tablet coat
  Hypromellose (HPMC 2910)
  Titanium dioxide (E171)
  Macrogol (PEG 400)
  Talc
  Indigo carmine aluminium lake (E132)
  Iron oxide black (E172)
  Iron oxide red (E172)

What Myfenax looks like and contents of the pack

Film-coated tablets
Pale purple, oval shaped film-coated tablet, debossed with "M500" on one side and plain on the other side.

Myfenax 500 mg film-coated tablets are available in PVC/PVdC-aluminium blisters in pack sizes of 50, 100, 150, 50 x 1 or 100 x 1 tablets and in multipacks containing 150 (3 packs of 50) tablets.

Not all pack sizes may be marketed.

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