

ACCOCEPT 180 (Mycophenolic Acid Gastro Resistant Tablets 180 mg)

ACCOCEPT 360 (Mycophenolic Acid Gastro Resistant Tablets 360 mg)

Mycophenolate Sodium Equivalent to Mycophenolic Acid (180 mg and 360 mg)

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What Accocept tablets are used for

Accocept tablets are used to stop the body's immune system from rejecting a kidney transplant. It is used together with other medicines containing ciclosporin and corticosteroids.

How Accocept tablets works

Accocept tablets contains a substance called mycophenolic acid. This belongs to a group of medicines called immuno suppressants.

These medicines help to reduce rejecting a kidney transplant along with other medicines containing ciclosporin and corticosteroids

Before you use Accocept tablets

- When you must not take it

Do not take Accocept tablets

- if you are allergic to Mycophenolic acid, Mycophenolate sodium, Mycophenolate Mofetil or any of the other ingredients of this medicine
- If you are pregnant.

- If you are breast-feeding.
- If you are a woman of child bearing potential and you are not using highly effective contraception methods.

If any of the above apply to you, tell your doctor without taking Accocept tablets.

- Before you start to take it

Talk to your doctor or pharmacist before taking Accocept tablets if:

- You have or have ever had serious digestive problems, such as stomach ulcer.
- You have a rare hereditary enzyme deficiency of hypoxanthine-guanine phosphoribosyl-transferase (HGPRT) such as Lesch-Nyhan or Kelley-Seegmiller syndrome.

- 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:

- medicines used to treat viral infections such as aciclovir or ganciclovir.
- antacids that contain magnesium and aluminium.
- activated charcoal used to treat digestive problems such as diarrhoea, upset stomach, and gas.
- other immunosuppressant medicines such as azathioprine or tacrolimus.
- medicines used to treat high blood cholesterol levels such as cholestyramine.

You should also tell your doctor if you plan to have any vaccinations.

Accocept tablets with food, drink and alcohol:

Accocept tablets can be taken with or without food. You need to choose whether to take your tablets with or without food and then take them in the same way each day. This is to make sure that the same amount of your medication is absorbed into your body each day. As a safety precaution, do not take Accocept tablets with alcohol.

Pregnancy and breast-feeding:

If you are a woman you should make sure that you are not pregnant, by means of a negative pregnancy test, before you start taking Accocept tablets. If you are a woman, your doctor should advise you about contraception before you start taking Accocept tablets. You must use contraception before and while taking it and for 6 weeks after you have stopped taking it. Tell your doctor straight away if you become pregnant during treatment with Accocept tablets.

Do not breast-feed during treatment with Accocept tablets or for 6 weeks after you have stopped taking Accocept tablets.

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

If you are a sexually active man it is recommended to use condoms during treatment, and for a total of 90 days after your last dose of Accocept tablets. In addition, your female partners are recommended to use highly effective contraception during your treatment and for a total of 90 days after the last dose of Accocept tablets.

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Children:

The use of Accocept tablets in children and adolescents is not recommended due to lack of data.

How to use Accocept tablets

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

- How much to use

Your doctor will tell you how much Accocept tablets to take each day. The recommended dose is 720 mg (four 180 mg or two 360 mg tablets) administered twice daily (1,440 mg daily dose).

- When to use it

Accocept tablets must be taken twice a day, once in the morning and once in the evening same as instructed by your doctor. It is always advisable to take doses at the same time each day. It will have the best effect and it will also help you to remember when to take Accocept tablets.

Swallow the tablets whole with a glass of water. Do not break or crush the tablets. Do not take any tablets that are broken or split.

- How long to use it

You should take Accocept tablets regularly. You should continue Accocept tablets treatment for as long as your doctor has told you. Do not stop your treatment without your doctor's advice.

Treatment will continue for as long as you need immunosuppression to stop your body rejecting your transplant.

- If you forget to take it

Take it as soon as you remember and then go back to taking it as you would normally and if it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

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

- If you take too much (overdose)

Immediately contact your doctor for advice or go to your nearest Accident and Emergency centre if you think that you or anyone else may have taken too much Accocept tablets, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Accocept tablets

- Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking Accocept tablets. Tell your doctor if you become pregnant while taking Accocept tablets. Visit your doctor regularly so that they can check on your progress.

- Things you must not do

Do not stop taking Accocept tablets 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 give Accocept tablets 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.

Patients should not donate blood during therapy or for at least 6 weeks following discontinuation of Mycophenolate.

Men should not donate semen during therapy or for at least 90 days following discontinuation of Mycophenolate.

- Things to be careful of

- Accocept tablets lower the skin's level of protection from the sun. This increases the risk of skin cancer. You should limit your exposure to sunlight and ultraviolet (UV) light by covering exposed skin areas as much as possible and regularly applying sunscreen with a high protective factor. Ask your doctor for advice on protection from the sun.
- if you already had hepatitis B or C mycophenolic acid may increase the risk of these re-appearing. Your doctor may perform blood analysis and check for symptoms of these diseases. If you experience any symptoms (yellow skin and eyes, nausea, loss of appetite, dark urine) you should tell your doctor immediately.
- if you get a persistent cough or become breathless, especially when taking other immunosuppressants, you should tell your doctor straight away.
- if you get any signs of infection (such as fever or a sore throat) or unexpected bruising or bleeding you should tell your doctor straight away.
- your doctor may want to check your white blood cell count during treatment with Accocept tablets, and will tell you whether you can continue taking Accocept tablets.

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- The active substance, mycophenolic acid, is not the same as other similar-sounding medicines such as Mycophenolate Mofetil. You should not switch between medicines unless your doctor tells you to.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Elderly patients may experience more side effects due to a reduced immune defense.

Some effects could be serious:

- signs of infection including fever, chills, sweating, feeling tired, drowsy, or lack of energy. If you are taking Accocept tablets you may be more likely to get viral, bacterial and fungal infections than usual. Such infections could affect various parts of your body, but the parts most commonly affected are the kidneys, bladder, upper and/or lower airways.
- vomiting blood, black or bloody stools, stomach or intestinal ulcer.
- swelling of your glands, development of a new skin growth or enlargement of an existing skin growth, or changes in an existing mole. As can happen in patients taking immunosuppressants, a very small number of Accocept tablets patients have developed cancer of the skin or lymph nodes.

If you experience any of the above after taking Accocept tablets, talk to your doctor straight away.

Other side effects may include:

- Very common
- diarrhoea

- low level of white blood cells, calcium (hypocalcaemia) and potassium (hypokalemia)
- high level of uric acid in the blood (hyperuricemia)
- high blood pressure (hypertension)
- pain in joints (arthralgia)
- anxiety

Common

- low level of red blood cells which can result in tiredness, breathlessness and looking pale (anaemia)
- unexpected bleeding and bruising (possible signs of a low level of blood platelets)
- headache
- abdominal or stomach pain, inflammation of the lining of the stomach, abdominal bloating, constipation, indigestion, wind (flatulence), loose stools, feeling sick (nausea), being sick (vomiting)
- tiredness, fever
- abnormal results of liver or kidney function tests
- respiratory infections.
- high level of potassium in the blood (hyperkalemia)
- low level of magnesium in the blood (hypomagnesemia)
- dizziness
- low blood pressure (hypotension)
- shortness of breath (dyspnea)
- acne
- weakness (asthenia)
- muscle pain (myalgia)
- swollen hands, ankles or feet (oedema peripheral)
- cough
- itching

Uncommon

- fast heartbeat (tachycardia) or irregular heart beat (ventricular extrasystoles), fluid in the lungs (pulmonary oedema)
- a growth that looks like a sac (cyst) containing fluid (lymph) (lymphocele)
- trembling, difficulty in sleeping
- redness and swelling of eyes (conjunctivitis), blurred vision
- wheezing
- belching, bad breath, bowel blockage (ileus), lip ulcers, heartburn, tongue discoloration, dry mouth, inflammation of the gums, inflammation of the pancreas leading to severe upper stomach pain (pancreatitis), blockage of the salivary glands, inflammation of the inner lining of the abdomen (peritonitis)
- infection of the bones, blood and the skin
- blood in urine, damage to the kidney, pain and difficulty passing urine
- hair loss, skin bruising
- inflammation of the joints (arthritis), back pain, muscle cramps
- loss of appetite, increased level of lipids (hyperlipidemia), sugar (diabetes), cholesterol (hypercholesterolemia), or decreased level of phosphate in the blood (hypophosphatemia)
- signs of flu (such as tiredness, chills, sore throat, aching joints or muscles), swelling of ankles and feet, feeling thirsty or weak
- strange dreams, believing things that aren't true (delusions)
- inability to get or keep an erection.
- cough, difficulty breathing, painful breathing (possible symptoms of interstitial lung disease)

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This is not a complete list of all possible side effects. If you get any side effects talk to your doctor or pharmacist.

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.moh.gov.my [Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Accocept tablets

- Storage

Do not store above 30 °C. Store in the original package in order to protect from moisture.

Keep the Accocept tablets out of the sight and reach of children.

Do not store the medicine, in a bathroom or near a sink.

Do not leave Accocept tablets in the car or on windowsills.

- Disposal

If your doctor tells you to stop taking Accocept tablets, or the products have passed their expiry date, ask your pharmacist what to do with any medicine that is left over.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

Product description

- What it looks like

Accocept tablets 180mg are Lime Green colored, round shaped, biconvex bevelled edged enteric-coated tablets imprinted with M1 on one side with black ink and plain on the other side.

Accocept tablets 360mg are Peach colored, oblong shaped, biconvex, enteric-coated tablets imprinted with M2 on one side with black ink and plain on the other side.

- Ingredients

- Active Ingredient Mycophenolate Sodium Equivalent to Mycophenolic Acid

- Inactive Ingredient
Microcrystalline Cellulose,
Croscarmellose Sodium,
Povidone K-30,
Talc,
Colloidal Anhydrous Silica,
Magnesium Stearate,
Opacode Black S-1-17823,
Isopropanol

Accocept tablets 180mg ACRYL-EZE Green 93O510003
Accocept tablets 360mg ACRYL-EZE Pink 93O54222

- MAL number:

Accocept tablets 180mg :
MAL20046116AZ

Accocept tablets 360mg :
MAL20046117AZ

Manufacturer

Intas Pharmaceuticals Limited.
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Product Registration Holder

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