

Mycockem Capsule 250 mg (MYCOPHENOLATE MOFETIL CAPSULES USP)

Mycophenolate Mofetil (250mg)

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What Mycockem is used for

MYCOKEM CAPSULE are used to prevent your body rejecting a transplanted kidney, heart or liver. MYCOKEM CAPSULE is used together with other medicines known as ciclosporin and corticosteroids.

How Mycockem works

These hard gelatin capsules contain 250mg of the active ingredient Mycophenolate Mofetil. This belongs to a group of medicines called "immunosuppressants". These medication works by lowering your body's immune system activity.

Before you use Mycockem

When you must not use it:

- MYCOKEM CAPSULE should not be given to women of child bearing potential who are not using highly effective contraception
- MYCOKEM CAPSULE treatment should not be initiated in women of child bearing potential without providing a pregnancy test result to rule out unintended use in pregnancy
- MYCOKEM CAPSULE should not be used during pregnancy unless there is no suitable alternative treatment to prevent transplant rejection
- MYCOKEM CAPSULE should not be given to women who are breastfeeding.

If any of the above apply to you (or you are not sure), talk to your doctor straight away before taking MYCOKEM CAPSULE.

Taking other medicines

Please inform your doctor or pharmacist if you are taking/using other medicines or have recently taken/used other medicines,

even if these were obtained without a prescription. Are you taking medicines that contains

-Acyclovir, Ganciclovir (for treatment of viral infection)

-colestyramine (for the treatment of patients with high blood cholesterol)

-rifampicin, norfloxacin, metronidazole, ciprofloxacin, amoxicillin + clavulanic acid (antibiotic)

-antacids

-Ciclosporin A, Tacrolimus (medicine that suppresses the immune)

-phosphate binders (used in patients with chronic renal failure to reduce the absorption of phosphate)

-or any other medicines (including those you can buy without a prescription), that your doctor does not know about?

- Do you need vaccinations (live vaccines)? Your doctor will advise you which vaccination is suitable for you.

Pregnancy and breastfeeding

Do not take MYCOKEM CAPSULE if you are breast-feeding.

You must not use MYCOKEM CAPSULE during pregnancy unless clearly indicated by your doctor.

Your doctor should advise you about using contraception before taking MYCOKEM CAPSULE, whilst taking MYCOKEM CAPSULE, and for 6 weeks after you have stopped taking MYCOKEM CAPSULE. This is because MYCOKEM CAPSULE may cause spontaneous abortions or damage, including problems with development of the ears, to your unborn baby.

Tell your doctor straight away if you are pregnant, breast-feeding, become pregnant or plan to start a family in the near future.

Driving and using machines

MYCOKEM CAPSULE has not been shown to impair your ability to drive or use machines.

How to use Mycockem

- Swallow your CAPSULE whole with a glass of water.

The initial dose of Mycockem should be given as soon as possible following kidney, heart and liver transplant. Do not break or crush them and do not take any capsules that have broken open or split. Avoid contact with any powder that spills out from damaged capsules. If a capsule breaks open accidentally, wash any powder from your skin with soap and water. If any powder gets into your eyes or mouth, rinse thoroughly with plenty of plain, fresh water.

How much to take

Kidney Transplant

Adults: The recommended daily dose is 2 grams a day (1gm twice a day)

Heart Transplant

Adults: The recommended daily dose is 3 grams a day (1.5gm twice a day)

Liver Transplant

Adults: The recommended daily dose is 3 grams a day (1.5gm twice a day)

How long to take it

The treatment will continue for as long as you need immune suppression to prevent your transplanted organ from being rejected.

If you forget to take it

As soon as you remember, take the missed dose, unless it is nearly time for the next dose. Never take two doses at the same time.

If you take too much (overdose)

Tell your doctor or contact the nearest hospital, taking the medicine or this leaflet with you.

While you are using it

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use MYCOKEM CAPSULE to treat any other complaints unless your doctor tells you to.

Do not take MYCOKEM CAPSULE if You are pregnant or breast feeding. Tell your doctor immediately if you think you are pregnant.

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The effect of sunlight

Mycophenolate reduces your body's defences. As a result, there is an increased risk of skin cancer. Limit the amount of sunlight and UV light you get. Do this by: wearing protective clothing which also covers your head, neck, arms and legs using a sunscreen with a high protection factor.

Things to be careful of

Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicines, even those not prescribed as stated under Section "Taking other medicines"

Side Effects

Like all medicines, MYCOKEM CAPSULE can have side effects, although not everybody gets them.

Some of the more usual problems are diarrhoea, fewer white cells and/or red cells in your blood, infection and vomiting. Your doctor will do regular blood tests to monitor any changes in the number of your blood cells or changes in the levels of any of the substances carried in your blood, e.g. sugar, fat, cholesterol.

MYCOKEM CAPSULE reduces your body's own defense mechanisms to stop you rejecting your transplanted kidney, heart or liver. Consequently your body will not be as good as normal at fighting infections. So if you are taking MYCOKEM CAPSULE you may therefore catch more infections than usual, such as infections of the brain, skin, mouth, stomach and intestines, lungs and urinary tract.

As can happen in patients taking this type of medicine, a very small number of MYCOKEM CAPSULE patients have developed cancer of the lymphoid tissues and skin.

Children aged less than 6 years old may be more likely than adults to have side effects such as diarrhoea, infections, fewer white cells and fewer red cells in the blood.

Elderly patients aged more than 65 years old may be more likely to have side effects such as infections, bleeding in the gastric area and water in lungs

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet whilst you are taking MYCOKEM CAPSULE, please tell your doctor or pharmacist. However, do not stop taking your medicine unless you have discussed this with your doctor first. 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 nptra.gov.my (Consumers > Reporting > Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage & Disposal of Mycokem

Keep out of the reach and sight of children. Do not store above 30° C. Store in the original package in order to protect from moisture. 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

White to off white granular powder filled in size "1" blue coloured cap, brown coloured body hard gelatin capsules imprinted "266" on body with black ink.

The capsules are available in blister pack of 1 x 10 & 10 x 10 Capsules.

Ingredients

Active Ingredient

The active substance is Mycophenolate Mofetil.

Inactive Ingredient

Croscarmellose sodium, Povidone K- 90, Pre gelatinized maize starch, Magnesium Stearate, and Size '1' empty capsule shell.

MAL Number: MAL17055011AZ

Manufacturer & Product Registration Holder

Manufacturer

Alkem Laboratories Ltd, Village Thana, Baddi, Dist: Solan, Himachal Pradesh, 173205 India

H.O: Alkem House, Senapati Bapat Marg, Lower Parel, Mumbai, 400013 India

Product Registration Holder

Ascend Laboratories Sdn Bhd, Level 25, Menara Hong Leong, No. 6, Jalan Damanlela, Bukit Damansara, 50490 Kuala Lumpur, Malaysia

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