PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

MYCOCEPT 250 (capsules)

Mycophenolate mofetil

Sugar free

Read all of this leaflet carefully before you start taking MYCOCEPT 250.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- MYCOCEPT 250 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What MYCOCEPT 250 is and what it is used for
2. What you need to know before you take MYCOCEPT 250
3. How to take MYCOCEPT 250
4. Possible side effects
5. How to store MYCOCEPT 250
6. Contents of the pack and other information

1. What MYCOCEPT 250 is and what it is used for

MYCOCEPT 250 contains mycophenolate mofetil, which belongs to a group of medicines called "immunosuppressants". MYCOCEPT 250 is used to prevent rejection of the transplanted organ following a kidney, heart or liver transplant.

MYCOCEPT 250 should be used together with other medicines:

- Ciclosporin and corticosteroids.

2. What you need to know before you take MYCOCEPT 250

WARNING

MYCOCEPT 250 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 MYCOCEPT 250 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 MYCOCEPT 250. See also further information in this section under "Warnings and precautions" and "Pregnancy, breastfeeding and fertility".

Do not take MYCOCEPT 250:

- If you are hypersensitive (allergic) to mycophenolate mofetil, mycophenolic acid or any of the other ingredients in 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 MYCOCEPT 250 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, breastfeeding and fertility").
- If you are breastfeeding.

Paediatric patients who have received cardiac (heart) and hepatic (liver) transplants should not take MYCOCEPT 250.

Do not take MYCOCEPT 250 if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking MYCOCEPT 250.

Warnings and precautions

Special care should be taken with MYCOCEPT 250.

Before taking this medicine, tell your doctor:

- If you are allergic to anything or if you have a history of mycophenolate mofetil or mycophenolic acid hypersensitivity. You may experience severe allergic reactions with MYCOCEPT 250.
- If you have a sign of infection such as a fever or sore throat.
- If you have any unexpected bruising or bleeding.
- If you have ever had a problem with your digestive system, such as a stomach ulcer.
- If you are planning to become pregnant or if you fall pregnant while taking MYCOCEPT 250.
- If you are going to be vaccinated/immunised, while taking MYCOCEPT 250.
- If you have problems with the liver.
- If you are taking any medicine for heartburn (antacids).

If any of the above apply to you (or you are not sure), talk to your doctor straight away before taking MYCOCEPT 250.

The effect of sunlight:

MYCOCEPT 250 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.

Donating blood and semen:

You must not donate blood during treatment with MYCOCEPT 250 and for at least 6 weeks after stopping treatment. Men must not donate semen during treatment with MYCOCEPT 250 and for at least 90 days after stopping treatment.

Other medicines and MYCOCEPT 250:

Always tell your healthcare professional if you are taking any other medicine (This includes complementary or traditional medicines). This is because MYCOCEPT 250 can affect the way some other medicines work. In addition, other medicines can affect the way MYCOCEPT 250 works.

Tell your doctor if you are using any of the following medicines:

- Azathioprine or other medicines, which suppress your immune system – given after a transplant operation.
- Heartburn medicines (antacids) or proton pump inhibitors – used for acid problems in your stomach such as indigestion.
- Cholestyramine – used to treat high cholesterol.
- Rifampicin – an antibiotic used to prevent and treat infections such as tuberculosis (TB).
- Phosphate binders – used by people with chronic kidney failure to reduce how much phosphate gets absorbed into their blood.
- Antibiotics – used to treat bacterial infections.
- Isavuconazole – used to treat fungal infections.
- Telmisartan – used to treat high blood pressure.
- Aciclovir or ganciclovir – used to treat viral infections.

- Tacrolimus – used to treat viral infections.
- If you are going to be vaccinated/ immunised while taking MYCOCEPT 250.

MYCOCEPT 250 with food and drink:

Taking food and drink has no effect on your treatment with MYCOCEPT 250.

Pregnancy, breastfeeding and fertility:

Pregnancy:

You should not use MYCOCEPT 250 if you are pregnant.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking MYCOCEPT 250.

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 MYCOCEPT 250, you must inform your doctor immediately. However, keep taking MYCOCEPT 250 until you see him or her.

Mycophenolate mofetil, the active component of MYCOCEPT 250, causes a very high frequency of miscarriage (50 %) and of severe birth defects (23 to 27%) in the unborn baby. Birth defects which have been reported include anomalies of ears, eyes, face (cleft lip/palate), development of fingers, 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.

Breastfeeding:

You should not use MYCOCEPT 250 if you are breastfeeding your baby. This is because small amounts of the medicine can pass into the mother's milk.

Fertility:

Contraception in women taking MYCOCEPT 250:

If you are a woman who could become pregnant you must use an effective method of contraception with MYCOCEPT 250.

This includes:

- Before you start taking MYCOCEPT 250.
- During your entire treatment with MYCOCEPT 250.
- For 6 weeks after you stop taking MYCOCEPT 250.

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.

Contraception in men taking MYCOCEPT 250:

The available evidence does not indicate an increased risk of malformations or miscarriage if the father takes MYCOCEPT 250. 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 MYCOCEPT 250.

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

Driving and using machines:

MYCOCEPT 250 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.

3. How to take MYCOCEPT 250

Do not share medicines prescribed for you with any other person.
Always take MYCOCEPT 250 exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
If you have the impression that the effect of MYCOCEPT is too strong or too weak, talk to your doctor or pharmacist.

The amount of MYCOCEPT 250 that you should take depends on the type of transplant you have had. The usual doses are shown below. Treatment will continue for as long as you need to prevent you from rejecting your transplant organ.

Kidney transplant:

Adults:

The first dose is given within 3 days of the transplant operation.
The usual adult dose is four MYCOCEPT 250 capsules twice a day for prevention of kidney transplant rejection.
Take 4 capsules in the morning and then 4 capsules in the evening.

Children (aged 3 months to 18 years):

The usual dose for children in prevention of kidney transplant rejection depends on how big the area of the body is. Your doctor will decide the most appropriate dose based on the child's body surface area. The usual dose is 3 MYCOCEPT 250 capsules twice a day.

Heart transplant:

Adults:

The first dose is given within 5 days of the transplant operation.

The usual adult dose for prevention of heart transplant rejection is 6 MYCOCEPT 250 capsules twice daily.

Take 6 capsules in the morning and then 6 capsules in the evening.

Children:

There is no information for the use of MYCOCEPT 250 in children with a heart transplant.

Liver transplant:

Adults:

The first dose of oral MYCOCEPT 250 will be given to you at least 4 days after the transplant operation and when you are able to swallow oral medicines.

The usual adult dose for prevention of liver transplant rejection is 6 MYCOCEPT 250 capsules twice daily.

Take 6 capsules in the morning and then 6 capsules in the evening.

Children:

There is no information for the use of MYCOCEPT 250 in children with a liver transplant.

Taking MYCOCEPT 250:

Swallow your capsules whole with a glass of water:

- Do not break or crush them
- Do not take any capsules that have broken open or split.

Take care not to let any powder from inside a broken capsule get into your eyes or mouth:

- If this happens, rinse with plenty of plain water.

Take care not to let any powder from inside a broken capsule get onto your skin:

- If this happens, wash the area thoroughly with soap and water.

If you take more MYCOCEPT 250 than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Also do this if someone else accidentally takes your medicine. Take the medicine pack with you.

Your doctor or pharmacist will treat the side effects symptomatically.

If you forget to take MYCOCEPT 250:

Take the missed dose as soon as possible. However, if it is almost time for your next dose, continue to take the next capsule at the usual time. Do not take a double dose. If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you stop taking MYCOCEPT 250:

Do not stop taking MYCOCEPT 250 unless your doctor tells you to. If you stop your treatment, you may increase the chance of rejection of your transplant organ.

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

4. Possible side effects

MYCOCEPT 250 can have side effects.

Not all side effects reported for MYCOCEPT 250 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MYCOCEPT 250, please consult your doctor, pharmacist or other healthcare professional for advice.

Contact your doctor immediately if you experience any of the following 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).

Usual problems:

Some of the more usual problems are diarrhoea, fewer white cells or red cells in your blood, infection and vomiting. Your doctor will do regular blood tests to check for any changes in:

• the number of your blood cells or signs of infections

Children may be more likely than adults to have some side effects. These include diarrhoea, infections, fewer white cells and fewer red cells in the blood.

Fighting infections:

MYCOCEPT 250 reduces your body's defences. This is to stop you rejecting your transplant. As a result, your body will not be as good as normal at fighting infections. This means you may catch more infections than usual. This includes infections of the brain, skin, mouth, stomach and gut, lungs and urinary system.

Lymph and skin cancer:

As can happen in patients taking this type of medicine (immune suppressants), a very small number of MYCOCEPT 250 patients have developed cancer of the lymphoid tissues and skin.

General unwanted effects:

You may get general side effects affecting your body as a whole. These include serious allergic reactions (such as anaphylaxis, angioedema), fever, feeling very tired, difficulty sleeping, pains (such as stomach, chest, joint or muscle), headache, flu symptoms and swelling.

These side effects have been reported and are frequent:

- Infections, including but not limited to sepsis (a serious infection that causes your immune system to attack your body), gastrointestinal candidiasis (overgrowth of your normal

bacteria in your stomach and small intestine), viral, bacterial and fungal infections, including urinary tract infection and herpes virus infections.

- Diarrhoea.
- Vomiting and or nausea.
- Stomach pain.
- Leukopenia (reduced white blood cells in your blood), anaemia (reduced healthy red blood cells in your blood), thrombocytopenia (low levels of platelets in your blood).
- Infection of the wound.
- Osteomyelitis (a serious infection of the bone).
- Upper respiratory tract infections (infections of the upper airways).
- Thrush (*Candida*) infections of the skin, mouth and vagina.
- Gastrointestinal infections (infections in the stomach and small intestine).
- Neoplasms (new and abnormal growth of cells, which may include cancers), including different skin cancers, Kaposi's sarcoma (a type of cancer affecting the lining of blood and lymph vessels), lymphoproliferative disorder (an overproduction of a certain type of white blood cell, lymphocytes), benign neoplasm of skin (unusual growths on the skin, which are non-cancerous).
- Neoplasms (new and abnormal growth of cells, which may include cancers), including different skin cancers, Kaposi's sarcoma (a type of cancer affecting the lining of blood and lymph vessels), lymphoproliferative disorder (an overproduction of a certain type of white blood cell, lymphocytes), benign neoplasm of skin (unusual growths on the skin, which are non-cancerous)
- Lymphocele (a collection of leaked lymph fluid).
- Abnormally low (lymphopenia, neutropenia) or high (leucocytosis) levels of a certain types of white blood cells).
- Lymphadenopathy (a disease of the lymph nodes, whereby they are abnormal in size and consistency).

- Pancytopenia (abnormally low levels of all three types of blood cells: red blood cells, white blood cells, and platelets).
- Bleeding
- Bleeding under the skin
- Anorexia (weight loss and difficulty to gain weight).
- Hyperlipidaemia (high levels of fat in your blood), hypercholesterolemia (high levels of cholesterol in your blood).
- Diabetes, hyperglycaemia (high levels of glucose in the blood).
- Thirst
- Hyperphosphatemia (high levels of phosphate in the blood).
- High (hyperkalaemia) or low (hypokalaemia) levels of potassium in the blood.
- Hypomagnesaemia (abnormally low levels of magnesium in the blood).
- Hypocalcaemia (abnormally low levels of calcium in the blood).
- Acidosis (when body fluids contain too much acid).
- Hyperuricemia (high levels of uric acid in the blood), gout.
- Feeling agitated.
- Feeling confused.
- Feeling depression or anxious.
- Thinking abnormal thoughts.
- Insomnia (being unable to sleep).
- Headache.
- Convulsions (fits).
- Somnolence (feeling sleepy and drowsy).
- Feeling dizzy.
- Hallucinations
- Paraesthesia (feeling of pins and needles).
- Trembling uncontrollably (tremors).
- Hypertonia (muscle stiffness and difficulty to stretch).

- Myasthenic syndrome (muscle weakness).
- Dysgeusia (taste disturbances).
- Blurred vision.
- Conjunctivitis (inflammation or swelling of inner layer of the eyelid, often referred to as “pink eye”).
- Ear pain
- Deafness
- Ringing in the ear
- Tachycardia (abnormally fast heartbeat).
- Pulmonary oedema (fluid in the lungs or inside the chest).
- Raised pressure in the lungs (pulmonary hypertension)
- Unexpected loss of heart function (cardiac arrest)
- Irregular heartbeat (ventricular extrasystoles).
- Low (hypotension) or high (hypertension) blood pressure.
- Vasodilatation (widening of the blood vessels).
- Cough. Talk to your doctor if you develop a persistent cough or breathlessness
- Wheezing, difficult breathing (dyspnoea).
- Asthma
- Collapsing of the lung
- Swelling or tenderness of the tummy.
- Constipation.
- Dyspepsia (indigestion), gastro-oesophageal reflux disease (a condition where stomach acid comes up into the oesophagus).
- Flatulence (passing gas).
- Eructation (burping).
- Gastritis (inflammation of the protective lining of the stomach), colitis (inflammation of the inner lining of the colon), oesophagitis (inflammation of the lining of the oesophagus).
- Loose stools.

- Ileus (lack of movement somewhere in the intestines that leads to a build-up and potential blockage of food material).
- Ulcers in the stomach (peptic ulcer), small intestine (duodenal ulcer).
- Gastrointestinal haemorrhage (bleeding in the gastrointestinal tract, anywhere from the mouth to the rectum).
- Peritonitis (inflammation of the peritoneum, the lining of the inner wall of the abdomen and cover of the abdominal organs).
- Gingival hyperplasia (overgrowth of gum tissue around the teeth).
- Stomatitis (inflammation of the mouth and lips).
- Hernia (abnormal bulging of an organ)
- Infection of the bile ducts
- Dark stools
- Difficulty swallowing
- Collection of fluid in your abdomen
- Hepatitis (inflammation of the liver).
- Jaundice (yellowing of the skin and whites of the eyes)
- Hyperbilirubinemia (abnormally high bilirubin (the product of red blood cells being broken down) levels in blood).
- Alopecia (hair loss).
- Skin hypertrophy (thickening of the skin).
- Rash.
- Acne.
- Sweating
- Growth of male-pattern hair on women (on face, chest and back)
- Arthralgia (joint pain).
- Leg cramps
- Muscle weakness
- Weakened bones

- Renal tubular necrosis (when cells within the kidney tubes die).
- Urethral stricture (narrowing of the urethra).
- Renal impairment (kidney failure).
- Blood in the urine
- Increased blood urea levels (determined by blood tests)
- Low urine output
- Frequent urination
- Frequent urination at night
- Loss of bladder control
- Swelling of the scrotum
- Fatigue (feeling tired).
- Fever.
- Influenza like feeling.
- Oedema (swelling, owing to excess fluid beneath the skin).
- Pain.
- Asthenia (feeling weak and without energy).
- Chills.
- Pale skin
- Impotence.
- Abnormal liver function tests, increased liver enzymes in the blood.
- Abnormal kidney function tests.
- Increased levels of the substance, lactate dehydrogenase, in the blood.
- Weight decreased.
- Serious allergic reactions (such as anaphylaxis and angioedema).
- Difficulty sleeping.
- Flu symptoms.
- Cold sores.
- Shingles.

- Skin growths.
- Itching.
- Blood in urine.
- Liver disorder.
- Loss of appetite.
- Feeling dizzy, drowsy or numb.
- Muscle spasms.
- Changes in your mood or thoughts.
- Pneumonia (serious lung infection with fever, chills, shortness of breath, cough, phlegm and occasionally blood).
- Sinus problems.

These side effects have been reported and are less frequent:

- Pancreatitis (inflammation of the pancreas).
- Halitosis (bad breath).
- Subileus (partial obstruction of the intestines).
- Tongue discolouration.
- Dry mouth.
- Contusion (bruising).
- Shortness of breath.

These side effects have been reported with unknown frequencies:

- Intestinal villous atrophy (destruction of your intestinal villi, the tiny fingers of cells that absorb nutrients from food).
- Agranulocytosis (dangerously low levels of specific type of white blood cells called neutrophils).
- Bone marrow depression (fewer blood cells are made in the marrow).
- Pure Red Cell Aplasia (PRCA) (fewer red blood cells are made in the bone marrow).

- Abnormal neutrophil morphology (a defect, whereby neutrophils, a type of white blood cell, do not develop normally).
- Spontaneous abortions.
- Congenital malformations (birth defects).
- Interstitial lung disease, pulmonary fibrosis (conditions where the lung tissue becomes damaged and scarred, making breathing more difficult).
- Bronchiectasis (the airways of the lungs becoming damaged and widened).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of MYCOCEPT 250.

Suspected side effects can also be reported directly to the Holder of Certificate of Registration (HCR) via the link: https://pvi1j.solutions.iqvia.com or the e-mail address, adverse.event.sac@sandoz.com.

5. How to store MYCOCEPT 250

- Store at or below 30 ºC. Protect from light and moisture.
- Store in the original container.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use after the expiry date printed on the carton and blister or container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MYCOCEPT 250 contains

The active ingredient is mycophenolate mofetil.

Inactive ingredients in the capsule are

Capsule Core:

Croscarmellose sodium

Povidone (K-90F)

Starch, pregelatinised

Magnesium stearate

Capsule shell:

Body composition:

Gelatine

Red iron oxide (E172)

Titanium dioxide (E172)

Yellow iron oxide (E172)

Cap Composition:

FD & C Blue #2 (E132)

Gelatine

Titanium dioxide

What MYCOCEPT 250 looks like and contents of the pack

Capsules (blue opaque cap and orange opaque body containing white to off white coloured powder).

100 capsules packed in a white opaque PVC/PE/PVdC/Al blister in a cardboard carton or in a HDPE container with polypropylene caps.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

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Sandoz SA Customer Call Centre 0861 726 225 (SANCAL)

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