Proposed Clean Patient Information Leaflet

WARNING: INFECTIONS AND CANCER

Mycophenolate reduces your body's defenses. As a result, your body will not be as good as normal at fighting infections and there is an increased risk of infection and the possible development of lymphoma (cancer of the lymph nodes and lymphatic system) and other cancers, especially of the skin.

WARNING: BIRTH DEFECTS AND MISCARRIAGE

Birth defects and miscarriages have been reported with use of mycophenolate in pregnancy.

If you are a woman who could become pregnant, you must provide a negative pregnancy test before starting treatment. Your doctor may request more than one test to ensure you are not pregnant before starting treatment.

Whether you are a man or woman taking MYCOCEPT 500, you and your sexual partner must follow the contraception advice given to you by your doctor.

SCHEDULING STATUS

S4

Please read this leaflet carefully before taking MYCOSEPT 500 tablets.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- MYCOCEPT 500 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.

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

MYCOSEPT 500 (Film-coated tablets)

1. WHAT MYCOCEPT 500 CONTAINS

The active ingredient is:

Each film-coated tablet contains 500 mg mycophenolate mofetil.

Inactive ingredients:

Microcrystalline cellulose, croscarmellose sodium, povidone (K-90F), magnesium stearate, talc and Opadry purple.

MYCOSEPT 500 tablets are sugar free.

2. WHAT MYCOCEPT 500 IS USED FOR

MYCOCEPT 500 is used in combination with other medicines to prevent the body from rejecting organs in patients receiving kidney, liver or heart transplants. The dosage and duration of the treatment will be unique to your particular condition and will be decided by your doctor.

3. BEFORE YOU TAKE MYCOCEPT 500

Do not take:

- If you are hypersensitive (allergic) to the active substance, mycophenolate mofetil, or any of the ingredients.
- If you are pregnant or while you are breastfeeding (see “PREGNANCY and BREASTFEEDING”).

Take special care with MYCOCEPT 500:

- Inform your doctor if you take any medication as this may interact with MYCOCEPT 500

- You should limit the exposure to sunlight and UV light by wearing protective clothing and using sunscreen with high protection factor while taking MYCOCEPT 500, as skin diseases may develop.
- While taking MYCOCEPT 500 you may develop infections.
- Inform your doctor immediately if you develop unexpected bruising or bleeding.
- Your doctor will request blood tests during your treatment.
- Vaccinations using live virus may be less effective.
- Inform your doctor if you have digestive system problems or disease.
- Inform your doctor if you have serious kidney problems.
- Elderly patients may experience an increased risk of side effects or negative effects compared to younger adult patients.

Pregnancy and breastfeeding:

Do not use MYCOCEPT 500 if you are pregnant, planning to become pregnant or breastfeeding your baby. MYCOCEPT 500 is excreted into breast milk and may affect your baby. Please consult your doctor, pharmacist or healthcare practitioner for advice.

Women who are capable of becoming pregnant must have a negative pregnancy test before starting treatment with MYCOCEPT 500

Tell your doctor straight away if:

- You think you may be pregnant
- You are breastfeeding
- You plan to start a family in the near future

You must always use an effective method of birth control:

- Before you start taking MYCOCEPT 500

- During your entire treatment with MYCOCEPT 500
- For 6 weeks after you stop taking MYCOCEPT 500

You should talk to your doctor about the most suitable methods for birth control for you based on your individual situation.

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)).

Driving and using machinery:

MYCOCEPT 500 is not expected to affect your ability to drive a car or operate machinery. Do take care until you know how MYCOCEPT 500 affects you.

Taking MYCOCEPT 500 with food and drink:

MYCOCEPT 500 can be taken with or without food and should be swallowed whole with a glass of water. Do not crush MYCOCEPT 500 tablets.

Taking other medicines with MYCOCEPT 500*:*

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of MYCOCEPT 500 with these medicines may cause undesirable interactions. Consult your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop.

The use of MYCOCEPT 500 with the following medicines may cause some interactions:

- Aciclovir, valaciclovir; ganciclovir, valganciclovir (antiviral medicines)

- Cholestyramine (used for high cholesterol levels in the bloodstream)
- Antacids with magnesium and aluminium hydroxides
- Azathioprine (medicine used to suppress the immune system)
- Ciclosporin (medicine used to suppress the immune system)
- The effectiveness of oral contraceptives may be decreased. Use additional birth control methods (See **"PREGNANCY and BREASTFEEDING"**)
- Probenecid (medicine used to treat high levels of uric acid in the blood)
- Tacrolimus (medicine used to suppress the immune system)

4. HOW TO TAKE MYCOCEPT 500

Take MYCOCEPT 500 exactly as directed by your doctor. Please consult your doctor or pharmacist if you are unsure.

Kidney Transplant:

Adult: You will receive you first dose within 72 hours after your transplant operation. The recommended dose is 2 tablets in the morning and 2 tablets in the evening.

Heart Transplant:

Adult: You will receive your first dose within 5 days after your transplant operation. The recommended dose is 3 tablets in the morning and 3 tablets in the evening.

Children: MYCOCEPT 500 should not be used in children in heart transplants.

Liver Transplant:

Adult: You will receive you first dose within 4 days after your transplant operation. The recommended dose is 3 tablets in the morning and 3 tablets in the evening.

Children: MYCOCEPT 500 should not be used in children in liver transplants.

It is very important that you complete the full course of treatment as prescribed by your doctor.

If you take more MYCOCEPT 500 than you should:

In the event of an overdosage contact your doctor or pharmacist immediately. If neither is available, seek help at the nearest hospital or poison control centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take your MYCOCEPT 500:

If you missed a dose, take it as soon as you remember. If it is almost time for you next dose, skip the missed dose and continue to take the tablet or tablets at the usual time. Do not take a double or larger dose to make up for the forgotten individual doses. If you have trouble remembering when to use your medicine, ask your pharmacist for advice.

5. POSSIBLE SIDE EFFECTS

MYCOCEPT 500 may have side effects.

Not all side effects reported for MYCOCEPT 500 are included in this leaflet.

Should your general health worsen while taking MYCOCEPT 500, please consult your doctor, pharmacist or other health care professional for advice.

Stop taking MYCOCEPT 500 and get emergency help immediately if any of the following side effects occur:

- Fast or irregular breathing and/or heartbeat
- Hive-like swelling on face, eyelids, mouth, lips or tongue
- Shortness of breath or difficulty breathing

- Headaches
- Irregular sleep patterns
- Skin growths.
- Allergy reactions
- Increased blood sugar levels
- Dehydration
- Muscle spasms
- Drowsiness
- Seizures (fits)
- Numbness or tingling of the skin
- Abnormal vision
- Jaundice- yellowing of the skin and eyes.
- Confusion
- Swelling or infection of the lining the eyelids

These are all very serious side effects. You may need urgent medical attention. All of these very serious side-effects are very rare.

Tell your doctor as soon as possible if you notice any of the following:

- Depression
- Anxiety
- Changes in thoughts or mood swings
- Sleeplessness
- Vomiting
- Abdominal pain

- Diarrhoea
- Nausea
- Constipation
- Indigestion
- Flatulence
- Bowel obstruction
- Rash
- Joint pain
- Swelling
- Chills
- Pain
- Feeling unwell
- Weakness

These are all mild, side-effects of MYCOCEPT 500

Your doctor will also perform regular blood tests to monitor any changes in the number of you blood cells and other substances. You may get infections of the skin, mouth, stomach, intestines, lungs and urinary tract. Your body may react to the treatment and presents as fever, difficulty in sleeping, pain of the stomach, chest, joints and muscles, headache, pain on passing urine, flu symptoms, and swelling.

If any of these side effects persists or worsens please inform your doctor or healthcare professional as soon as possible.

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

5. STORING AND DISPOSING OF MYCOCEPT 500

- Store at or below 25 °C
- Keep in outer carton until required for use.
- Protect from light and moisture
- **KEEP ALL MEDICINES OUT OF REACH OF CHILDREN**
- Do not use the tablets after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist

6. PRESENTATION OF MYCOCEPT 500

Mycocept 500 film-coated tablets are packed into 5 x White Opaque PVC/PE/PVDC Aluminium foil blister strips of 10 tablets each inside an outer cardboard box.

7. IDENTIFICATION OF MYCOCEPT 500

Mycocept 500: Lavender coloured, film-coated, biconvex tablet, plain on both the sides.

8. REGISTRATION NUMBER

43/32.2/0241

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Sandoz SA (Pty) Ltd.[1]

72 Steel Road, Spartan

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11. DATE OF PUBLICATION

Date of registration: 07 December 2012

Date of most recent approval of patient information leaflet: 07 December 2012

[1] Company registration no.: 1990/001979/07