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PACKAGE INSERT FOR Mycophenolate Alkem 250 mg AND 500 mg

SCHEDULING STATUS
S4

PROPRIETARY NAME (and dosage form)
Mycophenolate Alkem 250 mg (capsules)
Mycophenolate Alkem 500 mg (film coated tablets)

COMPOSITION
Active ingredient:
Mycophenolate Alkem 250 mg: Each capsule contains 250 mg mycophenolate mofetil.
Mycophenolate Alkem 500 mg: Each film coated tablet contains 500 mg mycophenolate mofetil.

Inactive ingredients:
Mycophenolate Alkem 250 mg: Croscarmellose sodium, pregelatinised starch, povidone, magnesium stearate, gelatine, sodium lauryl sulphate and the following colourants: titanium dioxide, FD&C blue No. 2, red iron oxide and yellow iron oxide.
Mycophenolate Alkem 500 mg: Croscarmellose sodium, povidone, microcrystalline cellulose, magnesium stearate and Instacoat ICG-U-10130 (consisting of hypromellose, macrogol, titanium dioxide, red iron oxide, black iron oxide and yellow iron oxide).

Sugar free.

PHARMACOLOGICAL CLASSIFICATION
A.32.2 Other (immuno-suppressants)

PHARMACOLOGICAL ACTION
Pharmacodynamic properties
Mycophenolate mofetil (MMF), a prodrug, is the 2-morpholinoethyl ester of mycophenolic acid (MPA) and is rapidly hydrolysed to MPA. MPA, the active metabolite is a selective, uncompetitive, and reversible inhibitor of inosine monophosphate dehydrogenase, and therefore inhibits the *de novo* pathway of guanosine nucleotide synthesis without incorporation into DNA. MPA has more potent cytostatic effects on lymphocytes than on other cells because T- and B-lymphocytes are critically dependent for their proliferation on *de novo* synthesis of purines, whereas other cell types can use salvage pathways.
MPA inhibits proliferative responses of T- and B-lymphocytes to both mitogenic and allospecific stimulation. Addition of guanosine or deoxyguanosine reverses the cytostatic effects of MPA on lymphocytes. MPA also suppresses antibody formation by B-lymphocytes. MPA prevents the glycosylation of lymphocyte and monocyte glycoproteins that are involved in intercellular adhesion to endothelial cells, and may inhibit recruitment of leukocytes into sites of inflammation and graft rejection. Mycophenolate mofetil does not inhibit early events in the activation of human peripheral blood mononuclear cells, such as the production of interleukin-1 (IL-1) and interleukin-2 (IL-2), but blocks the coupling of these events to DNA synthesis and proliferation.

Pharmacokinetic properties
Mycophenolate mofetil is rapidly and extensively absorbed after oral administration with the mean absolute bioavailability of 94 %. It undergoes rapid and complete metabolism to MPA after oral administration. The prodrug is cleared from the blood within a few minutes. The active metabolite, MPA, is in turn metabolised to the inactive phenolic glucuronide, MPAG, by glucuronyl transferase. Food has no effect on the extent of absorption of mycophenolate; however the maximum plasma concentrations of MPA were decreased by 40 % in the presence of food. The mean half-life of MPA after oral doses of mycophenolate mofetil is 17,9 hours.
MPA is highly bound, 97 %, to plasma albumin at relevant clinical concentrations, and 82 % for the inactive metabolite MPAG at concentration ranges normally seen in stable renal transplant patients. Higher concentrations of MPAG compete with MPA that may result in decreased MPA binding to albumin.
Renal clearance of 93 % (less than 1 % as MPA and 87 % as MPAG) is the primary route of elimination through tubular excretion and glomerular filtration.
Faecal excretion is responsible for the elimination of 6 % of the dose. MPA and MPAG are usually not removed by haemodialysis, however at high MPAG plasma concentrations (> 100 µg/ml) small amounts are removed.
Plasma concentrations of both MPA and MPAG are increased in patients with renal impairment.

Special populations:
Patients with severe renal impairment:
Multiple dosing of mycophenolate mofetil in patients with severe chronic renal impairment has not been studied.
Mean plasma MPA AUC after a single oral dose in subjects with severe chronic renal impairment (glomerular filtration rate < 25 ml/min/1,73 m^2), was 28 - 75 % higher than that observed in normal healthy subjects or subjects with lesser degrees of renal impairment. In addition, the mean single-dose plasma MPAG AUC was 3 - 6 fold higher in subjects with severe renal impairment than in subjects with mild renal impairment or normal healthy subjects, consistent with the known renal elimination of MPAG.

Patients with delayed renal graft function post-transplant:
In patients with delayed renal graft function post-transplant, mean MPA AUC_{0-12} was comparable to that seen in post-transplant patients without delayed renal graft function. Mean plasma MPAG AUC_{0-12} was 2 - 3 fold higher than in post-transplant patients without delayed renal graft function.
In patients with primary renal non-function following renal transplantation, plasma accumulation of MPA was minimal.

Patients with hepatic impairment:
In volunteers with alcoholic cirrhosis, hepatic MPA glucuronidation processes were relatively unaffected by hepatic parenchymal disease.

Children aged < 18 years:
Pharmacokinetic parameters in paediatric renal transplant patients (ranging from 1 year to 18 years of age) given 600 mg/m^2 mycophenolate mofetil orally twice daily, achieved MPA AUC values similar to those seen in adult renal transplant patients receiving mycophenolate mofetil at a dose of 1 g twice daily in the early and late post-transplant period. MPA AUC values across age groups were similar in the early and late post-transplant period.

INDICATIONS
Mycophenolate Alkem is indicated for the prophylaxis of organ rejection in patients receiving allogeneic renal, hepatic or cardiac transplants.
Mycophenolate Alkem should be used concomitantly with ciclosporin and corticosteroids.

CONTRAINDICATIONS
Hypersensitivity to mycophenolate mofetil, mycophenolic acid or any other component of Mycophenolate Alkem.
Pregnancy and lactation.

WARNINGS
Patients on Mycophenolate Alkem therapy should limit the exposure to sunlight and UV light by wearing protective clothing and using sunscreen with high protection factor. There is an increased risk of developing lymphomas and other malignancies, particularly of the skin in patients receiving Mycophenolate Alkem as part of an immuno-suppressive regimen, which appears to be related to the intensity and duration of immuno-suppression rather than to the use of any specific agent.
There can also be an increased susceptibility to infection, including opportunistic infections, fatal infections and sepsis during over suppression of the immune system.
Patients receiving Mycophenolate Alkem should have complete blood counts (CBC), weekly during the first month, twice monthly for the second and third months of treatment, then once a month through the remainder of the first year. Neutropenia should be monitored in these patients, as it may be related to Mycophenolate Alkem itself, concomitant medications, viral infections, or some combination of these causes.
Treatment with Mycophenolate Alkem may need to be stopped if severe neutropenia develops (ANC < 1,0 x 10^3/µl).
Patients receiving Mycophenolate Alkem should be instructed to immediately report any evidence of infection, unexpected bruising or bleeding to their medical practitioner.
There is also an increased risk of activation of latent viral infections. These include JC virus-associated progressive multifocal leukoencephalopathy, sometimes fatal, and BK virus-associated nephropathy, which can lead to renal graft loss.
During treatment with Mycophenolate Alkem, vaccinations may be less effective and the use of live attenuated vaccines should be avoided, due to the increased risk of infection. Intra-uterine devices should be used with caution in patients who are on Mycophenolate Alkem treatment for the same reason.
The risk-benefit should be considered when active digestive system disease is present, because mycophenolate mofetil has been associated with an increased incidence of digestive system adverse events, including infrequent cases of gastrointestinal tract ulceration, haemorrhage and perforation.
Mycophenolate Alkem should be administered with caution in these patients.

INTERACTIONS
Aciclovir, valaciclovir, ganciclovir or valganciclovir: increases in MPAG and aciclovir plasma concentrations were observed when Mycophenolate Alkem was administered concomitantly with these medicines, compared to their plasma concentrations when administrated alone. MPAG plasma concentrations as well as the plasma concentrations of these antivirals are increased in the presence of impaired renal function when administered alone. Therefore the potential exists for these medicines to compete for tubular secretion, thus resulting in further increases in concentration when administered concomitantly.
Cholestyramine and concomitant use of Mycophenolate Alkem may decrease the plasma concentration of MPA as a result of interruption of enterohepatic recirculation of MPA/G possibly caused by intestinal binding with cholestyramine resulting in reduced Mycophenolate Alkem efficacy.
Antacids with magnesium and aluminium hydroxides may decrease the absorption of Mycophenolate Alkem.
Concomitant administration of azathioprine and Mycophenolate Alkem is not recommended, due to both having the potential to cause bone marrow suppression.
Ciclosporin pharmacokinetics is unaffected when used simultaneously with Mycophenolate Alkem. However, in stable renal transplant patients (using Mycophenolate Alkem 1 gram twice per day) where ciclosporin is replaced with tacrolimus, there is about a 30 % increase in MPA plasma AUC and about 20 % decrease in MPAG plasma AUC. The dose of Mycophenolate Alkem should not exceed 1 gram twice a day, for patients on tacrolimus. Patients should be carefully observed and managed appropriately. Very limited pharmacokinetic data are available for hepatic transplant patients, with Mycophenolate Alkem in combination with tacrolimus.
Oral contraceptives: the AUC of levonorgestrel was significantly decreased with concomitant use with mycophenolate mofetil and additional birth control methods should be considered.
Medicines such as probenecid that undergo renal secretion, may increase the plasma concentrations of the metabolites of Mycophenolate Alkem.
Live vaccines: live vaccines should not be given to patients with impaired immune response. The antibody response to other vaccines may be diminished (see **WARNINGS**).
Rifampicin decreases exposure to mycophenolate (in patients not also taking ciclosporin); MPA concentrations should be monitored when rifampicin and Mycophenolate Alkem are used together.
In liver transplant patients, the bioavailability of MPA was reduced by concomitant administration of tobramycin and cefuroxime, apparently through inhibition of enterohepatic recycling of MPA by the antibacterials. Norfloxacin, metronidazole or a combination of the two, reduced exposure to MPA and MPAG, when given to healthy subjects receiving mycophenolate mofetil as in Mycophenolate Alkem. A similar reduction in concentration was noted with ciprofloxacin or amoxicillin and clavulanic acid.

PREGNANCY AND LACTATION
Mycophenolate Alkem is contraindicated in pregnancy and during breastfeeding.
The use of Mycophenolate Alkem in pregnancy is associated with an increased risk of first trimester pregnancy loss and an increased risk of congenital malformations (see **CONTRAINDICATIONS** and ***Special precautions***).
The use of Mycophenolate Alkem in pregnancy is associated with congenital abnormalities such as cleft lip and palate. Other anomalies include those of the distal limbs, heart, oesophagus and kidney, as well as malformations of the external ear.

Women of childbearing potential should have a negative pregnancy test within 1 week of starting Mycophenolate Alkem treatment. Women on Mycophenolate Alkem treatment should use effective contraception from at least 4 weeks prior to starting therapy, until 6 weeks after stopping treatment on Mycophenolate Alkem.

DOSAGE AND DIRECTIONS FOR USE
Administration of doses should not be greater than 1 gram twice a day, to renal transplant patients with severe chronic renal impairment and patients should be carefully observed.
No dose adjustment is required for patients with delayed renal graft function post-transplant, however, they should be carefully observed.

Dosage for prophylaxis of renal rejection
Adults: The initial dose of Mycophenolate Alkem should be given orally, within 72 hours following transplantation. The recommended dose is 1,0 gram administered twice a day.

Standard dosage for prophylaxis of cardiac rejection
Adults: A dose of 1,5 grams administered orally, twice a day (daily dose of 3 grams), is recommended for use in cardiac transplant patients. The initial dose should be given within 5 days following transplantation.
Children: No data are available for paediatric cardiac transplant patients.

Standard dosage for prophylaxis of hepatic rejection
Adults: Administration should be initiated as soon as possible after transplantation. A dose of 1,5 grams administered orally, twice a day (daily dose of 3 grams), is recommended for use in hepatic transplant patients.
Children: No data are available for paediatric hepatic transplant patients.

Special dosage instructions
Mycophenolate Alkem should be taken on an empty stomach and should be swallowed whole with a glass of water.
Mycophenolate Alkem 250 mg capsules should not be opened or crushed.
Mycophenolate Alkem 500 mg tablets should not be chewed or crushed.

Renal impairment: These patients should also be carefully observed. In patients with severe chronic renal impairment (glomerular filtration rate < 30 ml/min/1,73 m^2), outside of the immediate post-transplant period, doses greater than 1 gram, administered twice a day, should be avoided.
No data are available for cardiac or hepatic transplant patients with severe chronic renal impairment.

Delayed renal graft function post-transplant: No dose adjustments are needed in patients experiencing delayed renal graft function post-operatively.

Hepatic impairment: No dose adjustments are needed for renal transplant patients with severe hepatic parenchymal disease. No data are available for cardiac transplant patients with severe hepatic parenchymal disease.

Elderly: The recommended dose of 1 gram administered twice a day for renal transplant and 1,5 grams twice a day for cardiac transplant patients, is appropriate for elderly patients (see **WARNINGS**).

Neutropenia: Dosing with Mycophenolate Alkem should be interrupted or the dose reduced (absolute neutrophil count < 1,3 x 10^3/µl) (see **WARNINGS**).

SIDE EFFECTS AND SPECIAL PRECAUTIONS
Side effects:
Infections and infestations
Frequency unknown: Meningitis, infectious endocarditis

Blood and the lymphatic system disorders
Frequent: Anaemia (including hypochromic anaemia), leukocytosis, leukopenia, thrombocytopenia
Less frequent: Ecchymosis, polycythaemia, increased prothrombin time/INR, increased thromboplastin time
Frequency unknown: Aplastic anaemia, bone marrow depression, pure red cell aplasia

Endocrine disorders
Less frequent: Diabetes mellitus, parathyroid disorder, Cushing's syndrome

Metabolism and nutrition disorders
Frequent: Disturbances of electrolytes and blood lipids including hypercholesterolaemia, hyperglycaemia, hyperkalaemia, hypokalaemia, hypomagnesaemia, hyponatraemia, hypophosphataemia
Less frequent: Acidosis (metabolic or respiratory), increased alkaline phosphatase, dehydration, hyperlipidaemia, weight gain

Psychiatric disorders
Less frequent: Convulsions, emotional lability, hallucinations, neuropathy, abnormal thinking, delirium, hyperaesthesia, psychosis
Frequency unknown: Agitation, depression, anxiety

Nervous system disorders
Frequent: Dizziness, insomnia, tremor
Less frequent: Paraesthesia, somnolence

Eye disorders
Less frequent: Amblyopia, abnormal vision, conjunctivitis, cataract

Ear and labyrinth disorders
Less frequent: Deafness

Cardiovascular disorders
Frequent: Hypertension, hypotension
Less frequent: Angina pectoris, dysrhythmias, atrial fibrillation, cardiac arrest, congestive heart failure, postural hypotension, vasodilatation, bradycardia, pericardial effusion, tachycardia

Respiratory disorders
Frequent: Pneumonia, sinusitis
Less frequent: Asthma, pulmonary oedema, rhinitis, pharyngitis, bronchitis, pleural effusion, dyspnoea, coughing
Frequency unknown: Tuberculosis, atypical mycobacterial infection

Gastrointestinal disorders
Frequent: Diarrhoea, nausea, vomiting, constipation, dyspepsia
Less frequent: Gastrointestinal haemorrhage, oral moniliasis, gingivitis, gum hyperplasia, oesophagitis, stomatitis, pancreatitis
Frequency unknown: Colitis, intestinal villous atrophy

Hepato-biliary disorders
Less frequent: Hepatitis, elevated enzyme levels (ALT and AST), bilirubinaemia

Skin and subcutaneous tissue disorders
Less frequent: Acne, alopecia, benign neoplasm of skin, fungal dermatitis, hirsutism, skin carcinoma, skin hypertrophy (including actinic keratosis), skin ulcer, rash, herpes simplex

Musculoskeletal disorders
Less frequent: Leg cramps, myalgia, myasthenia, arthralgia, hypertonia

Renal and urinary disorders
Frequent: Haematuria, renal tubular necrosis, urinary tract infection, albuminuria, hydronephrosis, pyelonephritis
Less frequent: Dysuria, urinary frequency, urinary incontinence, urinary retention, oliguria, nocturia

General disorders
Frequent: Asthenia, fever, headache, infection, pain (includes abdominal, back and chest), peripheral oedema, sepsis
Less frequent: Cysts (including lymphocele and hydrocele), enlarged abdomen, facial oedema, flu syndrome, haemorrhage, malaise, pelvic pain, hernia, ascites

Special precautions
Mycophenolate Alkem is an IMPDH (inosine monophosphate dehydrogenase) inhibitor, therefore, it should be avoided in patients with rare hereditary deficiency of hypoxanthine-guanine phosphoribosyl-transferase (HGPRT) such as Lesch-Nyhan and Kelley-Seegmiller syndrome (see **WARNINGS**).
Elderly patients may be at an increased risk of adverse events compared to younger individuals.

Effects on ability to drive and use machines
Patients should avoid operating hazardous machines or driving motor vehicles, as Mycophenolate Alkem may cause somnolence and drowsiness.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Symptoms of overdosage:
See **SIDE EFFECTS AND SPECIAL PRECAUTIONS**.
Cardiac and hepatic transplant patients given doses of 4 to 5 grams per day appeared to have a higher rate of gastrointestinal intolerance including nausea, vomiting, and/or diarrhoea and occasional haematological abnormalities, principally neutropenia, leading to dose reduction or discontinuation, compared with patients taking 3 grams per day or less.
Treatment of overdosage:
Mycophenolate Alkem cannot be removed by haemodialysis.
Mycophenolate Alkem can be removed by bile acid sequestrants, such as cholestyramine, by increasing excretion of Mycophenolate Alkem.

IDENTIFICATION
Mycophenolate Alkem 250 mg (capsules): Size "1" capsule with a blue cap and a brown body with "266" printed with black ink on the body.
Mycophenolate Alkem 500 mg (tablets): Lavender coloured, caplet shaped, biconvex film coated tablet debossed with "265" on one side and plain on other side.

PRESENTATION
Mycophenolate Alkem 250 mg is packed into plain aluminium foil / white opaque PVC blister strips containing 10 capsules. 10 blister strips of 10 capsules each packed in an outer carton.
Mycophenolate Alkem 500 mg is packed into plain aluminium foil / white opaque PVC blisters strips containing 10 tablets. 5 blister strips of 10 tablets each packed in an outer carton.

STORAGE INSTRUCTIONS
Store at or below 25 °C. Protect from light and moisture. Keep blister strips in outer carton until required for use.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS
Mycophenolate Alkem 250 mg: 45/32.2/0219
Mycophenolate Alkem 500 mg: 45/32.2/0220

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Alkem Laboratories (Pty) Ltd.
Jankra Building, 2nd Floor
3 O.R. Tambo Drive
Potchefstroom 2531

DATE OF PUBLICATION OF THIS PACKAGE INSERT
5 December 2013

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PATIENT INFORMATION LEAFLET FOR Mycophenolate Alkem 250 mg AND 500 mg

SCHEDULING STATUS:
S4

PROPRIETARY NAME, STRENGTH and PHARMACEUTICAL FORM:
Mycophenolate Alkem 250 mg (capsules)
Mycophenolate Alkem 500 mg (film coated tablets)

Please read this leaflet carefully before taking Mycophenolate Alkem 250 mg capsules or Mycophenolate Alkem 500 mg tablets.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- Mycophenolate Alkem 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.

1. WHAT Mycophenolate Alkem CONTAINS:
Active ingredient:
Mycophenolate Alkem 250 mg : Each capsule contains 250 mg mycophenolate mofetil.
Mycophenolate Alkem 500 mg: Each film coated tablet contains 500 mg mycophenolate mofetil.
Inactive ingredients:
Mycophenolate Alkem 250 mg: Croscarmellose sodium, pregelatinised starch, povidone, magnesium stearate, gelatine, sodium lauryl sulphate and the following colourants: titanium dioxide, FD&C blue No. 2, iron oxide red and iron oxide yellow.
Mycophenolate Alkem 500 mg: Croscarmellose sodium, povidone, microcrystalline cellulose, magnesium stearate and Instacoat ICG-U-10130 (consisting of hypromellose, macrogol, titanium dioxide, red iron oxide, black iron oxide and yellow iron oxide).

Sugar free.

2. WHAT Mycophenolate Alkem IS USED FOR:
Mycophenolate Alkem is used to prevent the body from rejecting organs in patients receiving kidney, liver or heart transplants.

3. BEFORE YOU TAKE Mycophenolate Alkem:
Do not take Mycophenolate Alkem:
- If you are hypersensitive (allergic) to the active substance, mycophenolate mofetil, or any of the inactive ingredients (see **WHAT Mycophenolate Alkem CONTAINS**).
- If you are pregnant or breastfeeding.

Take special care with Mycophenolate Alkem:
- Elderly patients may experience an increased risk of side effects compared to younger adult patients.
- You should limit the exposure to sunlight and UV light by wearing protective clothing and using sunscreen with high protection factor while taking Mycophenolate Alkem, as skin diseases may develop.
- Your doctor will request blood tests during your treatment in order to monitor any blood changes.
- Do not receive live vaccines (immunisation) due to an increased risk of infection.
- Female patients should use intra-uterine devices (a form of birth control) with caution as it may also increase the risk of infection.
- While taking Mycophenolate Alkem you may develop infections. Inform your doctor immediately if you develop unexpected bruising or bleeding.
- Inform your doctor if you have an active digestive system disease. Mycophenolate Alkem is associated with an increased incidence of digestive system adverse events.

Taking Mycophenolate Alkem with food and drink:
Mycophenolate Alkem should be taken on an empty stomach and should be swallowed whole with a glass of water.

Pregnancy and breastfeeding:
If you are pregnant, planning to become pregnant or breastfeeding your baby while taking Mycophenolate Alkem, please consult your doctor. Mycophenolate Alkem is excreted into breast milk and may affect your baby.
The use of Mycophenolate Alkem during pregnancy is associated with birth defects in babies; especially of the ears, lip and cleft palate as well as the kidneys.

Driving and using machinery:
Mycophenolate Alkem may cause dizziness or sleepiness.
Do not drive a vehicle or operate any machinery until you know how Mycophenolate Alkem affects you.

Using other medicines with Mycophenolate Alkem:
If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of Mycophenolate Alkem 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.
Inform your doctor if you take any medication, as this may interact with Mycophenolate Alkem.
The use of Mycophenolate Alkem with the following medicines may cause undesirable interactions:
- Aciclovir, valaciclovir, ganciclovir or 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)
- Oral contraceptives (used to prevent unplanned pregnancies)
- Live vaccines (used to prevent certain diseases)
- Rifampicin (used to treat tuberculosis (TB))
- Tobramycin, cefuroxime, norfloxacin, ciprofloxacin, metronidazole, amoxicillin and clavulanic acid (used to treat bacterial infections)

Not all the medicines that may interact with Mycophenolate Alkem are listed above.

4. HOW TO TAKE Mycophenolate Alkem:
Mycophenolate Alkem should be taken exactly as directed by your doctor. Please consult your doctor or pharmacist if you are unsure.
Mycophenolate Alkem should be taken on an empty stomach and should be swallowed whole with a glass of water.
Do not open or crush Mycophenolate Alkem 250 mg capsules.
Do not chew or crush Mycophenolate Alkem 500 mg tablets.

Kidney transplant:
Adults: You will receive your first dose within 72 hours after your transplant operation.
The recommended dose is four Mycophenolate Alkem 250 mg capsules in the morning and four capsules in the evening
OR
Two Mycophenolate Alkem 500 mg tablets in the morning and two tablets in the evening.

Heart transplant:
Adults: You will receive your first dose within five days after your transplant operation. The recommended dose is six Mycophenolate Alkem 250 mg capsules in the morning and six capsules in the evening
OR
Three Mycophenolate Alkem 500 mg tablets in the morning and three in the evening.
Children: Mycophenolate Alkem is not recommended for children in heart transplants.

Liver transplant:
Adults: You will receive your first dose within four days after your transplant operation. The recommended dose is six Mycophenolate Alkem 250 mg capsules in the morning and six capsules in the evening
OR
Three Mycophenolate Alkem 500 mg tablets in the morning and three in the evening.
Children: Mycophenolate Alkem is not recommended for children in liver transplants.
It is very important that you complete the full course as prescribed by your doctor.

If you take more Mycophenolate Alkem 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 centre. Take this leaflet and any remaining capsules or tablets with you, so that the doctor knows what you have taken.

If you forget to take Mycophenolate Alkem:
If you missed a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue to take the capsule(s) or tablet(s) at the usual time.
Do not take a double or larger dose to make up for the forgotten individual doses.

5. POSSIBLE SIDE EFFECTS:
Mycophenolate Alkem may have side effects or undesired effects.
Not all side effects reported for Mycophenolate Alkem are included in this leaflet.

Should your general health worsen while taking Mycophenolate Alkem, please consult your doctor, pharmacist or other healthcare professional for advice.
Stop taking Mycophenolate Alkem and seek 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

These are all very serious side effects. You may have suffered an allergic reaction to Mycophenolate Alkem and need urgent medical attention.
Tell your doctor immediately if you experience any of the following side effects which may occur frequently (listed with the very serious / life threatening side effects first, followed by decreasing order of seriousness):
- Signs of blood disorders such as excessive tiredness, dizziness, unexplained bleeding, bruising or looking pale
- High or low blood pressure
- High levels of cholesterol (fat) in your blood (which is determined by a blood cholesterol test by your doctor)
- Diabetes (characterised by frequent urination, excessive thirst, unusual tiredness)
- Low potassium levels in your blood (characterised by vomiting, nausea, constipation, low blood pressure) or abnormally high potassium levels in your blood (characterised by nausea, unusual weakness or tiredness, muscle weakness)
- Abnormally low levels of magnesium in your blood (characterised by weakness, muscle cramps or irregular heart beats)
- Abnormally low levels of sodium (salt) in your blood (characterised by nausea and vomiting, headache, confusion, unusual weakness or tiredness, appetite loss, restlessness, irritability, muscle weakness, spasms or cramps)
- Abnormally low levels of phosphate in your blood (characterised by muscle dysfunction and weakness, irritability or confusion)
- Nervous excitement, anxiety, confusion, depression
- Blood in your urine
- Bladder infection (characterised by burning when you are urinating), difficulty with urination, white foam in your urine, intense pain in the area between your hips and ribs
- Pneumonia (inflammation of the lungs caused by a bacterial or viral infection, characterised by coughing, fever, shaking, chills, shortness of breath and sharp or stabbing chest pain during deep breaths)
- Sepsis (bacterial infection in your bloodstream or body tissues, characterised by fever, low body temperature and fast breathing)
- Dizziness, trouble in sleeping, trembling or shaking of hands or feet
- Swelling of lower legs or feet
- Diarrhoea, nausea, vomiting, constipation, heartburn
- Unusual weakness or tiredness, fever, headache, stomach pain, back pain, chest pain
- Hay fever

Tell your doctor immediately if you experience any of the following side effects which may occur less frequently (listed with the very serious / life threatening side effects first, followed by decreasing order of seriousness):
- Discolouration of the skin due to blood disorders
- Underactive thyroid gland (characterised by weight gain, unusual weakness and depression) or overactive thyroid gland (characterised by irritability, fast irregular heart beat, increased sweating and weight loss)
- Cushing's syndrome (high levels of cortisol, characterised by upper body obesity, a rounded face, increased fat around the neck and thinning arms and legs)
- Seizures (fits), mood changes, seeing or hearing things that do not exist, nerve damage (characterised by muscle weakness, cramps and spasms or tingling, numbness and pain), abnormal thinking, an abnormal increase in sensitivity to stimuli of your senses, loss of contact with reality
- Acidosis (too much acid in your body, after your doctor performed a urine test that checks your body's pH levels), dehydration (when your body loses more fluid than it takes in), increased weight
- Increased tightness of muscle tone
- Sensation of tingling, burning, pricking or numbness of the skin ("pins and needles"), sleepiness
- Vision disturbances, infection in the eye, cataract (cloudiness of the eye)
- Hearing loss
- Disturbances of your heart beat, heart disorders, heart failure, abnormally slow or fast heart beat
- Light-headedness when standing up from a lying or sitting position
- Asthma, lung disorders (characterised by difficulty breathing, coughing up blood (classically seen as pink, frothy sputum), excessive sweating, anxiety, pale skin, flu-like symptoms, chest pain)
- Blood in your stools, fungus infection in your mouth, inflammation of the gums, mouth, oesophagus or pancreas, overgrowth of the gum tissue
- Skin cancers
- Liver disease (characterised by yellow colouration of the skin and eyes)
- Painful or difficult urination, need to urinate more often than usual, loss of bladder control, production of abnormally small amounts of urine, excessive urination at night
- Feeling an abnormal lump beneath the skin, enlarged stomach, swelling of the face, flu-like symptoms, unusual weakness or tiredness, seeing or feeling a bulge in your stomach area, stomach pressure
- Leg cramps, muscle pain, joint pain, abnormal weakness of certain muscles
- Acne, temporary hair loss, skin rash, infection of the skin
- Runny nose, sore throat

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

6. STORING AND DISPOSING OF Mycophenolate Alkem:
Store at or below 25 °C.
Protect from light or moisture.
Keep blister strips in outer carton until required for use.
KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.
Do not use after the expiry date printed on the carton.
Return all unused medicine to your pharmacist.

7. PRESENTATION OF Mycophenolate Alkem:
Mycophenolate Alkem 250 mg is packed into plain aluminium foil / white opaque PVC blister strips containing 10 capsules. 10 blister strips of 10 capsules each packed in an outer carton.
Mycophenolate Alkem 500 mg is packed into plain aluminium foil / white opaque PVC blisters strips containing 10 tablets. 5 blister strips of 10 tablets each packed in an outer carton.

8. IDENTIFICATION OF Mycophenolate Alkem:
Mycophenolate Alkem 250 mg (capsules): Size "1" capsule with a blue cap and a brown body with "266" printed with black ink on the body.
Mycophenolate Alkem 500 mg (tablets): Lavender coloured, caplet shaped, biconvex film coated tablet debossed with "265" on one side and plain on other side.

9. REGISTRATION NUMBERS:
Mycophenolate Alkem 250 mg: 45/32.2/0219
Mycophenolate Alkem 500 mg: 45/32.2/0220

10. NAME AND ADDRESS OF REGISTRATION HOLDER:
Alkem Laboratories (Pty) Ltd.
Jankra Building, 2nd Floor
3 O.R. Tambo Drive
Potchefstroom 2531

11. DATE OF PUBLICATION:
5 December 2013

Alkem Laboratories Limited			
Product: Mycophenolate Tab-Cap Insert		Market: South Africa	Size: (L x H) 320 x 700 mm Folding Size: 160 x 21.875 mm
Itemcode: PT 2320	Version No: 00	Superseed No: NA	Mfg Location: Amaliya
Pantone No: ■ Black			Pack Size: NA
Component: Insert	Style: Folded	Substrate: Bible Paper 30 GSM (Front Back printing)	
Change Part No: NA	Pharmacode: 1919	Barcode: NA	GTIN No.: NA
Reason for Issue: New Artwork			Change Control No: NA
Initiated Date: 25/04/2k14			Modified Date: 19/05/2k14
Correction Version No.: 02			Date: 19/05/2k14

VOUBILJET VIR Mycophenolate Alkem 250 mg EN 500 mg

SKEDULERINGSTATUS
S4

EIENDOMSNAAM (en doseervorm)
Mycophenolate Alkem 250 mg (kapsules)
Mycophenolate Alkem 500 mg (filmbedekte tablette)

SAMESTELLING
Aktiewe bestanddeel:
Mycophenolate Alkem 250 mg: Elke kapsule bevat 250 mg mikofenolaatmofetil.
Mycophenolate Alkem 500 mg: Elke filmbedekte tablet bevat 500 mg mikofenolaatmofetil.

Onaktiewe bestanddele:
Mycophenolate Alkem 250 mg: Natriumkroskarmellose, vooraf-gegelatineerde stysel, povidoon, magnesiumstearaat, gelatien, natriumlourielsulfaat en die volgende kleurmiddels: titaandioksied, FD&C blue No. 2, rooi ysteroksied en geel ysteroksied.
Mycophenolate Alkem 500 mg: Natriumkroskarmellose, povidoon, mikrokristallyne sellulose, magnesiumstearaat en Instacoat ICG-U-10130 (wat bestaan uit hipromellose, makrogol, titaandioksied, rooi ysteroksied, swart ysteroksied en geel ysteroksied).

Suikervry.

FARMAKOLOGIESE KLASSIFIKASIE
A.32.2 Ander (Immuunonderdrukkers)

FARMAKOLOGIESE WERKING
Farmakodinamiese eienskappe
Mikofenolaatmofetil (MMF), 'n voorlopergeneesmiddel, is die 2-morfolinoëtielester van mikofenoliensuur (MPA) en word vinnig gehidroliseer na MPA. MPA, die aktiewe metaboliet, is 'n selektiewe, nie-kompeterende en omkeerbare inhibeerder van inosienmonofosfaatdehidrogenase en inhibeer gevolglik die *de novo* weg van guanosiennukleotiedsintese, sonder inkorporasie in die DNA. MPA het kragtiger sitostatiese effekte op limfosiete as op ander selle, omrede T- en B-limfosiete se vermeerdering krities afhanklik is van *de novo* sintese van puriene, terwyl ander seltipes herwinningsweë kan benut.
MPA inhibeer die proliferatiewe response van T- en B-limfosiete op beide mitogeniese en allospesifieke stimulasie. Die byvoeging van guanosien of deoksiguanosien keer die sitostatiese effek van MPA op limfosiete om. MPA onderdruk ook die vorming van teenliggame deur B-limfosiete. MPA voorkom die glikosilering van limfosiet- en monosietglikoproteïene, wat betrokke is by intersellulêre adhesie aan endoteelselle. Dit mag die werwing van leukosiete na plekke van inflammasie en gevolglike verwerping van die oorgeplante orgaan inhibeer. Mikofenolaatmofetil inhibeer nie die vroeë gebeure in die aktivering van menslike perifere bloed mononukleêre selle, soos die produksie van interleukien-1 (IL-1) en interleukien-2 (IL-2) nie, maar dit keer dat hierdie gebeure aan DNA sintese en proliferasie gekoppel word.

Farmakokinetiese eienskappe
Mikofenolaatmofetil word na orale toediening vinnig en breedvoerig geabsorbeer, met 'n gemiddelde absolute biobeskikbaarheid van 94 %. Na orale toediening, ondergaan dit vinnige en volledige metabolisme na MPA. Die voorlopergeneesmiddel word binne 'n paar minute uit die bloed opgeruim. Die aktiewe metaboliet, MPA, word op sy beurt deur glukuronieltransferase na die onaktiewe fenoliese glukuronied, MPAG, gemetaboliseer. Voedsel het geen effek op die mate van absorpsie van mikofenolaat nie. Die maksimum plasmakonsentrasies van MPA is egter met 40 % verlaag in die teenwoordigheid van kos. Die gemiddelde halfleeftyd van MPA na orale dosisse van mikofenolaatmofetil, is 17,9 uur.
Met 97 % is MPA teen relevante kliniese konsentrasies hoogs gebonde aan plasma-albumien en die onaktiewe metaboliet MPAG is 82 % gebind teen konsentrasiereikwydtes wat gewoonlik aangetref word by stabiele nieroorplantingspasiënte. Hoër konsentrasies MPAG wedywer met MPA, wat kan lei tot verlaagde MPA binding aan albumien.
Renale opruiming van 93 % (minder as 1 % as MPA en 87 % as MPAG) is die primêre roete van eliminasie deur tubulêre ekskresie en glomerulêre filtrasie. 6 % van die dosis word via die feses uitgeskei. MPA en MPAG word gewoonlik nie deur hemodialise verwyder nie, teen hoë MPAG plasmakonsentrasies (> 100 µg/ml) word klein hoeveelhede egter wel verwyder.
Plasmakonsentrasies van sowel MPA en MPAG is verhoog by pasiënte met renale inkorting.

Spesiale populasies:
Pasiënte met ernstige renale inkorting:
Veelvoudige dosering van mikofenolaatmofetil in pasiënte met ernstige chroniese renale inkorting is nie bestudeer nie.
Gemiddelde plasma MPA AOK na 'n enkele orale dosis in pasiënte met ernstige chroniese renale inkorting (glomerulêre filtrasietempo < 25 ml/min/1,73 m^2), was 28 – 75 % hoër as dit wat by normale, gesonde persone of persone met mindere grade van renale inkorting waargeneem is. Daarby was die gemiddelde enkeldosis plasma AOK van MPAG 3 – 6 keer hoër in persone met ernstige renale inkorting as in persone met ligte renale inkorting of normale gesonde persone, wat ooreenstem met die renale uitskeiding van MPAG, soos bekend is.

Pasiënte met vertraagde renale transplantaatfunksie na oorplanting:
In pasiënte met vertraagde renale transplantaatfunksie na oorplanting, was die gemiddelde MPA AOK_{0-12} vergelykbaar met dit wat na oorplanting waargeneem is by pasiënte sonder vertraagde renale transplantaatfunksie. Gemiddelde plasma MPAG AOK_{0-12} was 2 – 3 keer hoër as in pasiënte na oorplanting sonder vertraagde renale transplantaatfunksie.
Akkumulasie van MPA in die plasma was minimaal in pasiënte met primêre renale wanfunksie na nieroorplanting.

Pasiënte met hepatiese inkorting:
In vrywilligers met alkoholiese sirrose, was hepatiese MPA glukuronidasieprosesse relatief ongeaffekteer deur hepatiese parenchimale siekte.

Kinders onder die ouderdom van 18 jaar:
Farmakokinetiese parameters in pediatriese nieroorplantingspasiënte (in die reikwydte van 1 jaar tot 18 jaar) wie 600 mg/m^2 mikofenolaatmofetil oraal twee keer per dag gegee word, het MPA AOK waardes bereik soortgelyk aan die wat gesien word in volwasse nieroorplantingspasiënte, wie mikofenolaatmofetil teen 'n dosis van 1 g twee keer per dag ontvang het in die vroeë en laat periode na oorplanting. MPA AOK waardes oor ouderdomsgroepe heen, was soortgelyk in die vroeë en laat periode na oorplanting.

INDIKASIES
Mycophenolate Alkem word aangedui vir die voorkoming van orgaanverwerping in pasiënte wie allogeniese nier-, lewer- of hartoorplantings ontvang.
Mycophenolate Alkem behoort saam met siklosporien en kortikosteroïede gebruik te word.

KONTRA-INDIKASIES
Hipersensitiwiteit vir mikofenolaatmofetil of mikofenoliese suur, of enige ander bestanddeel van Mycophenolate Alkem.
Swangerskap en borsvoeding.

WAARSKUWINGS
Pasiënte op Mycophenolate Alkem terapie moet hul blootstelling aan sonlig en UV-lig beperk deur beskermende klere te dra en sonskerm met 'n hoë beskermingsfaktor te gebruik. Daar is 'n verhoogde risiko om limfome en ander kwaadaardighede te ontwikkel, veral van die vel, in pasiënte wie Mycophenolate Alkem as deel van 'n immuunonderdrukkende regimen ontvang. Dit lyk of dit verband hou met die intensiteit en duur van immuunonderdrukking, eerder as met die gebruik van enige spesifieke middel.
Daar kan ook 'n verhoogde vatbaarheid vir infeksie wees, insluitend opportunistiese infeksies, dodelike infeksies en sepsis, gedurende oormatige onderdrukking van die immuunsisteem.
Pasiënte wie Mycophenolate Alkem ontvang, behoort volbloedtellings (VBT) te ondergaan, weekliks gedurende die eerste maand, twee keer per maand vir die tweede en derde maande van behandeling, dan een keer per maand vir die res van die eerste jaar. Neutropenie moet in hierdie pasiënte gemoniteer word, aangesien dit verwant mag wees aan Mycophenolate Alkem self, medikasies wat gelyktydig toegedien word, virusinfeksies, of 'n kombinasie van hierdie oorsake.
Dit mag nodig wees om behandeling met Mycophenolate Alkem te staak indien erge neutropenie ontwikkel.
Pasiënte wie Mycophenolate Alkem ontvang, behoort aangesê te word om onmiddellik enige teken van infeksie, onverwagse kneusing of bloeding aan hul mediese praktisyn te rapporteer.
Daar is ook 'n verhoogde risiko dat latente virusinfeksies geaktiveer kan word. Dit sluit in JC-virusgeassosieerde progressiewe multifokale leukoenkefalopatie, soms dodelik, en BK-virusgeassosieerde nefropatie, wat kan lei tot verlies van renale transplantaat.
Gedurende behandeling met Mycophenolate Alkem, mag inentings minder effektief wees en die gebruik van lewendige, verswakte entstowwe moet vermy word weens die verhoogde risiko van infeksie. Om dieselfde rede moet intra-uteriene apparate met omsigtigheid gebruik word in pasiënte wie op Mycophenolate Alkem behandeling is.
Die verhouding van risiko tot voordeel moet oorweeg word wanneer aktiewe siekte van die spysverteringsisteem teenwoordig is, aangesien mikofenolaatmofetil geassosieer is met 'n verhoogde insidensie van newe-effekte van die spysverteringstelsel, insluitend minder dikwels gevalle van gastro-intestinale ulkusse, bloeding en perforasie. Mycophenolate Alkem moet versigtig aan hierdie pasiënte toegedien word.

INTERAKSIES
Asiklovir, valasiklovir, gansiklovir of valgansiklovir: verhogings in MPAG en asiklovir plasmakonsentrasies is waargeneem toe Mycophenolate Alkem gelyktydig met hierdie medisynes toegedien is, in vergelyking met hul plasmakonsentrasies wanneer alleen toegedien word. In die teenwoordigheid van nierontoereikendheid, word MPAG plasmakonsentrasie sowel as die plasmakonsentrasies van hierdie antivirale middels verhoog wanneer dit alleen toegedien word. Daar is gevolglik die potensiaal vir hierdie medisynes om te kompeteer vir tubulêre sekresie en dit veroorsaak 'n verdere verhoging in die konsentrasies van hierdie medisynes wanneer dit gelyktydig toegedien word.
Cholestiramien en die gelyktydige gebruik van Mycophenolate Alkem mag die plasmakonsentrasie van MPA verlaag, as gevolg van 'n onderbreking van enterohepatiese hersirkulasie van MPAG. Dit word moontlik veroorsaak deur intestinale binding met cholestiramien, wat lei tot verminderde Mycophenolate Alkem effektiwiteit.
Teensuurmiddels met magnesium- en aluminiumhidroksiede mag die absorpsie van Mycophenolate Alkem verminder.
Die gelyktydige toediening van asatioprien en Mycophenolate Alkem word nie aanbeveel nie, omdat beide die potensiaal het om beenmurgonderdrukking te veroorsaak.
Farmakokinetika van siklosporien word nie beïnvloed wanneer dit saam met Mycophenolate Alkem gebruik word nie. By stabiele nieroorplantingspasiënte (wie Mycophenolate Alkem 1 gram twee keer per dag gebruik), waar siklosporien vervang word met takrolimus, is daar egter 'n toename in MPA plasma AOK van ongeveer 30 % en ongeveer 20 % afname van MPAG plasma AOK. Vir pasiënte wie takrolimus gebruik, behoort die dosis Mycophenolate Alkem nie 1 gram twee keer per dag te oorskry nie. Pasiënte moet deeglik gemoniteer en op gepaste wyse bestuur word. Baie beperkte farmakokinetiese data is beskikbaar vir leweroorplantingspasiënte, met Mycophenolate Alkem in kombinasie met takrolimus.
Orale voorbehoedmiddels: die AOK van levonorgestrel is betekenisvol verlaag met die gelyktydige gebruik van mikofenolaatmofetil en bykomende geboortebeperkingsmetodes moet oorweeg word.
Medisynes soos probenesied wat renale sekresie ondergaan, mag die plasmakonsentrasies van die metaboliete van Mycophenolate Alkem verhoog.
Lewendige entstowwe: lewendige entstowwe moet nie aan pasiënte met ingekorte immuunrespons gegee word nie. Die teenliggaamrespons teenoor ander entstowwe mag verswak wees (kyk **WAARSKUWINGS**).
Rifampisien verminder die blootstelling aan mikofenolaat (in pasiënte wie nie siklosporien ook neem nie); MPA konsentrasies moet gemoniteer word wanneer rifampisien en Mycophenolate Alkem saam gebruik word.
In leweroorplantingspasiënte is die biobeskikbaarheid van MPA verminder deur gelyktydige toediening van tobramisien en kefuroksiem, skynbaar deur inhibisie van enterohepatiese hergebruik van MPA deur die antibakteriële middels. Norfloksasien, metronidasool of 'n kombinasie van die twee, het blootstelling aan MPA en MPAG verminder toe dit gegee is aan gesonde persone wie mikofenolaatmofetil, soos in Mycophenolate Alkem, ontvang. 'n Soortgelyke verlaging in konsentrasie is met siprofloksasien of amoksisillien en klavulaansuur waargeneem.

SWANGERSKAP EN BORSVOEDING
Mycophenolate Alkem word teenaangedui gedurende swangerskap en borsvoeding.
Die gebruik van Mycophenolate Alkem gedurende swangerskap is geassosieer met 'n verhoogde risiko van eerste trimester swangerskapverlies en 'n verhoogde risiko van kongenitale misvormings (kyk **KONTRA-INDIKASIES** en ***Spesiale voorsorgmaatreëls***).
Die gebruik van Mycophenolate Alkem tydens swangerskap word geassosieer met kongenitale abnormaliteite soos 'n gesplete lip en verhemelte. Ander anomalieë sluit in dié van distale ledemate, hart, esofagus en nier, sowel as misvormings van die eksterne oor.

10 mm

Vrouens wie nog kan swanger raak, moet 'n negatiewe swangerskapstoets hê binne 1 week voor begin word met Mycophenolate Alkem behandeling. Vrouens wie Mycophenolate Alkem behandeling ontvang, moet effektiewe voorbehoeding gebruik vanaf ten minste 4 weke voor aanvang van terapie, tot 6 weke na staking van behandeling met Mycophenolate Alkem.

DOSIS EN GEBRUIKSAANWYSINGS
Toediening van dosisse aan nieroorplantingspasiënte met ernstige chroniese renale inkorting behoort nie meer as 1 gram twee keer per dag te wees nie en pasiënte moet noukeurig dopgehou word. Dit is nie nodig om die dosis aan te pas vir pasiënte met vertraagde renale transplantaatfunksie nie, hulle moet egter deeglik gemoniteer word.

Dosis vir profilakse van renale verwerping
Volwassenes: Die aanvanklike dosis Mycophenolate Alkem moet oraal gegee word, binne 72 uur na oorplanting. Die aanbevole dosis is 1,0 gram twee keer 'n dag toegedien.

Standaard dosering vir die profilakse van kardiale verwerping
Volwassenes: 'n Dosis van 1,5 gram twee keer per dag oraal toegedien (daaglikse dosis van 3 gram), word aanbeveel vir gebruik in hartoorplantingspasiënte. Die aanvanklike dosis moet binne 5 dae na die oorplanting gegee word.
Kinders: Daar is geen data beskikbaar vir pediatriese hartoorplantingspasiënte nie.

Standaard dosering vir profilakse van hepatiese verwerping
Volwassenes: Toediening moet so gou as moontlik na oorplanting begin word. 'n Dosis van 1,5 gram twee keer per dag oraal toegedien (daaglikse dosis van 3 gram), word aanbeveel vir gebruik in leweroorplantingspasiënte.
Kinders: Daar is geen data beskikbaar vir pediatriese leweroorplantingspasiënte nie.

Spesiale doseringsinstruksies
Mycophenolate Alkem moet op 'n leë maag geneem word en met 'n vol glas water gesluk word.
Mycophenolate Alkem 250 mg kapsules moet nie oopgemaak of fyngedruk word nie.
Mycophenolate Alkem 500 mg tablette moet nie gekou of fyngedruk word nie.

Renale inkorting: Hierdie pasiënte moet ook noukeurig waargeneem word. By pasiënte met ernstige chroniese renale inkorting (glomerulêre filtrasietempo < 30 ml/min/1,73 m^2), buite die onmiddellike post-oorplantingsperiode, moet dosisse groter as 1 gram, twee keer per dag toegedien, vermy word.
Daar is geen data beskikbaar vir hart- of leweroorplantingspasiënte met ernstige chroniese renale inkorting nie.

Vertraagde renale transplantaatfunksie na oorplanting: Dit is nie nodig om die dosis aan te pas in pasiënte met vertraagde renale transplantaatfunksie na oorplanting nie.

Hepatiese inkorting: Dit is nie nodig om die dosis aan te pas vir nieroorplantingspasiënte met ernstige hepatiese parenchimale siekte nie. Daar is geen data beskikbaar vir hartoorplantingspasiënte met ernstige hepatiese parenchimale siekte nie.

Bejaardes: Die aanbevole dosis van 1 gram twee keer per dag toegedien vir nieroorplantingspasiënte en 1,5 gram twee keer per dag vir hartoorplantingspasiënte, is toepaslik vir bejaarde pasiënte (kyk **WAARSKUWINGS**).

Neutropenie: Dosering met Mycophenolate Alkem moet onderbreek word of die dosis verlaag word (absolute neutrofieltelling < 1,3 x 10^3/µl) (kyk **WAARSKUWINGS**).

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS
Newe-effekte:
Infeksies en infestasies
Frekwensie onbekend: Meningitis, aansteeklike endokarditis

Bloed- en die limfsisteemversteurings
Dikwels: Anemie (insluitend hipochromiese anemie), leukositose, leukopenie, trombositopenie
Minder dikwels: Bloedingsvlekke, polisitemie, verhoogde protrombientyd/INR, toename in tromboplastientyd
Frekwensie onbekend: Aplastiese anemie, beenmurgonderdrukking, suiwer rooisel aplasie

Endokrienversteurings
Minder dikwels: Diabetes mellitus, paratiroïedsteuring, Cushing se sindroom

Metabolisme en voedingsteurings
Dikwels: Versteurings van elektroliete en bloedlipiede, insluitend hipercholesterolemie, hiperglisemie, hiperkalemie, hipokalemie, hipomagnesemie, hiponatremie, hipofosfatemie
Minder dikwels: Asidose (metabolies of respiratories), verhoogde alkaliese fosfatase, dehidrasie, hiperlipidemie, massatoename

Psigiatriese steurings
Minder dikwels: Konvulsies, emosionele labiliteit, hallusinasies, neuropatie, abnormale denke, delirium, hiperestesie, psigose
Frekwensie onbekend: Prikkelbaarheid, depressie, angstigheid

Senuweesisteemversteurings
Dikwels: Duiseligheid, slaaploosheid, tremor
Minder dikwels: Parestesie, slaperigheid

Oogversteurings
Minder dikwels: Ambliopie, abnormale visie, konjunktivitis, katarak

Oor- en labirintversteurings
Minder dikwels: Doofheid

Kardiovaskulêre versteurings
Dikwels: Hipertensie, hipotensie
Minder dikwels: Angina pectoris, disritmieë, atriale fibrillasie, hartstilstand, kongestiewe hartversaking, posturale hipotensie, vasodilatasie, bradikardie, perikardiale effusie, tagikardie

Respiratoriese versteurings
Dikwels: Pneumonie, sinusitis
Minder dikwels: Asma, pulmonale edeem, rinitis, faringitis, brongitis, pleurale effusie, dispnee, hoes
Frekwensie onbekend: Tuberkulose, atipiese mikobakteriële infeksie

Gastro-intestinale versteurings
Dikwels: Diarree, naarheid, braking, hardlywigheid, dispepsie
Minder dikwels: Gastro-intestinale bloeding, orale moniliase, tandvleisontsteking, tandvleishiperplasie, esofagitis, stomatitis, pankreatitis
Frekwensie onbekend: Kolitis, intestinale villeuse atrofie

Hepato-biliêre versteurings
Minder dikwels: Hepatitis, verhoogde ensiemvlakke (ALT en AST), bilirubinemie

Vel- en subkutaneweefselversteurings
Minder dikwels: Aknee, alopesie, goedaardige neoplasma van die vel, fungale dermatitis, hirsutisme, velkarsinoom, velhipertrofie (insluitend aktiniese keratose), velulkus, uitslag, herpes simplex

Muskuloskeletale versteurings
Minder dikwels: Beenkrampe, mialgie, miastenie, artralgie, hipertonie

Nier- en urienwegversteurings
Dikwels: Hematurie, renale tubulêre nekrose, urienweginfeksie, albuminurie, hidronefrose, piëlonefritis
Minder dikwels: Disurie, urinêre frekwensie, urinêre inkontinensie, urienterughouding, oligurie, nokturie

Algemene versteurings
Dikwels: Astenie, koors, hoofpyn, infeksie, pyn (insluitend abdominaal, rug en borskas), perifere edeem, sepsis
Minder dikwels: Siste (insluitend limfoseel en hidroseel), vergrote buik, gesigsedeem, griepsindroom, bloeding, malaise, pelvispyn, breuke, askites (ophoping van vog in buikholte)

Spesiale voorsorgmaatreëls
Mycophenolate Alkem is 'n IMPDH (inosienmonofosfaatdehidrogenase) inhibitor, en moet gevolglik vermy word by pasiënte met 'n raar oorerflike tekort aan hipoxantien-guanienfosforibosieltransferase (HGPRT) soos Lesch-Nyhan- en Kelley-Seegmillersindroom (kyk **WAARSKUWINGS**).
Bejaarde pasiënte mag 'n verhoogde risiko van ongunstige effekte hê, in vergelyking met jonger individue.

Effekte op die vermoë om te bestuur en masjinerie te gebruik
Pasiënte moet vermy om gevaarlike masjinerie te hanteer of 'n motorvoertuig te bestuur, aangesien Mycophenolate Alkem slaperigheid en lomerigheid mag veroorsaak.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN
Simptome van oordosering:
Kyk **NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS**.
Dit het gelyk of hart- en leweroorplantingspasiënte wie dosisse van 4 tot 5 gram per dag ontvang, 'n hoër voorkoms van gastro-intestinale onverdraagsaamheid, insluitend naarheid, braking, en/of diarree en soms hematologiese abnormaliteite, hoofsaaklik neutropenie het, wat aanleiding gee tot verlaging van die dosis of staking van terapie, in vergelyking met pasiënte wie 3 gram of minder per dag neem.
Behandeling van oordosering:
Mycophenolate Alkem kan nie deur hemodialise verwyder word nie.
Mycophenolate Alkem kan deur galsuursekwestrante, soos cholestiramien, verwyder word, deur die uitskeiding van Mycophenolate Alkem te verhoog.

IDENTIFIKASIE
Mycophenolate Alkem 250 mg (kapsules): Grootte "1" kapsule met 'n blou doppie en 'n bruin romp met "266" in swart ink op die romp gedruk.
Mycophenolate Alkem 500 mg (tablette): Ligpers, kapletvormige, bikonvekse, filmbedekte tablet, met "265" aan die een kant ingepers en glad aan die ander kant.

AANBIEDING
Mycophenolate Alkem 250 mg word verpak in gewone aluminiumfoelie / wit ondeursigtige PVC stulpstroke wat 10 kapsules bevat. 10 stulpstroke met 10 kapsules elk word in 'n buitenste karton verpak.
Mycophenolate Alkem 500 mg word verpak in gewone aluminiumfoelie / wit ondeursigtige PVC stulpstroke wat 10 tablette bevat. 5 stulpstroke met 10 tablette elk word in 'n buitenste karton verpak.

BEWARINGSINSTRUKSIES
Bêre by of onder 25 °C. Beskerm teen lig en vog. Hou die stulpstroke in die buitenste karton tot benodig vir gebruik.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMERS
Mycophenolate Alkem 250 mg: 45/32.2/0219
Mycophenolate Alkem 500 mg: 45/32.2/0220

10 mm

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT
Alkem Laboratories (Pty) Ltd.
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DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET
5 Desember 2013

PASIËNTINLIGTINGSBLAD VIR Mycophenolate Alkem 250 mg EN 500 mg

SKEDULERINGSTATUS:
S4

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM:
Mycophenolate Alkem 250 mg (kapsules)
Mycophenolate Alkem 500 mg (filmbedekte tablette)

Lees asseblief hierdie inligtingsblad deeglik voordat begin word om Mycophenolate Alkem 250 mg kapsules of Mycophenolate Alkem 500 mg tablette te neem.
- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Indien jy enige verdere vrae het, vra asseblief jou dokter of jou apteker.
- Mycophenolate Alkem is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit mag skadelik wees vir hulle, selfs al het hulle dieselfde simptome as jy.

1. WAT Mycophenolate Alkem BEVAT:
Aktiewe bestanddeel:
Mycophenolate Alkem 250 mg: Elke kapsule bevat 250 mg mikofenolaatmofetil.
Mycophenolate Alkem 500 mg: Elke filmbedekte tablet bevat 500 mg mikofenolaatmofetil.
Onaktiewe bestanddele:
Mycophenolate Alkem 250 mg: Natriumkroskarmellose, vooraf-gegelatineerde stysel, povidoon, magnesiumstearaat, gelatien, natriumlourielsulfaat en die volgende kleurmiddels: titaandioksied, FD&C blue No. 2, rooi ysteroksied en geel ysteroksied.
Mycophenolate Alkem 500 mg: Natriumkroskarmellose, povidoon, mikrokristallyne sellulose, magnesiumstearaat en Instacoat ICG-U-10130 (wat bestaan uit hipromellose, makrogol, titaandioksied, rooi ysteroksied, swart ysteroksied en geel ysteroksied).

Suikervry.

2. WAARVOOR Mycophenolate Alkem GEBRUIK WORD:
Mycophenolate Alkem word gebruik om te voorkom dat die liggaam organe verwerp by pasiënte wie 'n oorgeplante nier, lewer of hart ontvang.

3. VOORDAT JY Mycophenolate Alkem NEEM:
Moenie Mycophenolate Alkem neem:
- Indien jy hipersensitief (allergies) vir die aktiewe bestanddeel, mikofenolaatmofetil, of enige van die onaktiewe bestanddele is nie (kyk **WAT Mycophenolate Alkem BEVAT**).
- Indien jy swanger is of borsvoed nie.

Neem spesiale sorg met Mycophenolate Alkem:
- Bejaarde pasiënte mag 'n verhoogde risiko vir newe-effekte ervaar, in vergelyking met jonger volwasse pasiënte.
- Jy moet blootstelling aan sonlig en UV-lig beperk deur beskermende klere te dra en sonskerm met 'n hoë beskermingsfaktor te gebruik terwyl Mycophenolate Alkem geneem word, aangesien velsiektes mag ontwikkel.
- Jou dokter sal bloedtoetse aanvra terwyl jy behandeling ondergaan, om enige verandering in die bloed te moniteer.
- Moet nie lewendige entstowwe (immunisasies) ontvang nie, weens 'n verhoogde risiko van infeksie.
- Vroulike pasiënte behoort intra-uteriene apparate ('n vorm van geboortebeperking) met omsigtigheid te gebruik, aangesien dit ook die risiko van infeksie mag verhoog.
- Jy mag infeksies ontwikkel terwyl Mycophenolate Alkem gebruik word. Lig jou dokter onmiddellik in indien jy onverwagse kneusing of bloeding ontwikkel.
- Lig jou dokter in indien jy 'n aktiewe siekte van die spysverteringstelsel het. Mycophenolate Alkem word geassosieer met 'n verhoogde insidensie van newe-effekte van die spysverteringstelsel.

Die neem van Mycophenolate Alkem met kos en drinkgoed:
Mycophenolate Alkem moet op 'n leë maag geneem word en met 'n vol glas water gesluk word.

Swangerskap en borsvoeding:
Indien jy swanger is, beplan om swanger te raak of jou baba borsvoed terwyl jy Mycophenolate Alkem neem, konsulteer asseblief jou dokter. Mycophenolate Alkem word in borsmelk uitgeskei en mag jou baba affekteer.
Die gebruik van Mycophenolate Alkem gedurende swangerskap word geassosieer met geboorte-afwykings by babas; veral van die ore, lippe en gesplete verhemelte, sowel as die niere.

Bestuur en die gebruik van masjinerie:
Mycophenolate Alkem mag duiseligheid of lomerigheid veroorsaak.
Moenie 'n voertuig bestuur of enige masjinerie hanteer totdat jy weet hoe Mycophenolate Alkem jou affekteer nie.

Die gebruik van ander medisynes met Mycophenolate Alkem:
Indien jy ander medisyne op 'n gereelde grondslag neem, insluitend komplementêre of tradisionele medisyne, mag die gebruik van Mycophenolate Alkem saam met hierdie medisyne ongewenste wisselwerkings veroorsaak. Raadpleeg jou dokter of apteker indien jy enige ander medisyne neem, insluitend enige wat jy by die apteek, supermark of gesondheidskoswinkel gekoop het.
Lig jou dokter in indien jy enige medikasie neem, aangesien dit wisselwerking met Mycophenolate Alkem kan hê.
Die gebruik van Mycophenolate Alkem saam met die volgende medisynes, mag ongewenste interaksies veroorsaak:
- Asiklovir, valasiklovir, gansiklovir of valgansiklovir (antivirale medisynes)
- Cholestiramien (gebruik vir hoë cholesterolvlakke in die bloedstroom)
- Teensuurmiddels met magnesium- en aluminiumhidroksiede
- Asatioprien (medisyne wat gebruik word om die immuunsisteem te onderdruk)
- Orale voorbehoedmiddels (gebruik om onbeplande swangerskappe te voorkom)
- Lewendige entstowwe (gebruik om sekere siektes te voorkom)
- Rifampisien (gebruik om tuberkulose (TB) te behandel)
- Tobramisien, kefuroksiem, norfloksasien, siprofloksasien, metronidasool, amoksisillien en klavulaansuur (gebruik om bakteriële infeksies te behandel)

Nie al die medisynes wat wisselwerking met Mycophenolate Alkem mag hê, is hierbo gelys nie.

4. HOE OM Mycophenolate Alkem TE NEEM:
Mycophenolate Alkem moet geneem word presies soos wat jou dokter voorgeskryf het. Konsulteer asseblief jou dokter of apteker indien jy onseker is.
Mycophenolate Alkem moet op 'n leë maag geneem word en heel gesluk word met 'n vol glas water.
Moet nie die Mycophenolate Alkem 250 mg kapsules oopmaak of stukkend druk nie.
Moet nie Mycophenolate Alkem 500 mg tablette kou of fyndruk nie.

Nieroorplanting:
Volwassenes: Jy sal jou eerste dosis binne 72 uur na jou oorplantingsoperasie ontvang.
Die aanbevole dosis is vier Mycophenolate Alkem 250 mg kapsules in die oggend en vier kapsules in die aand
OF
Twee Mycophenolate Alkem 500 mg tablette in die oggend en twee tablette in die aand.

Hartoorplanting:
Volwassenes: Jy sal jou eerste dosis binne vyf dae na jou oorplantingsoperasie ontvang. Die aanbevole dosis is ses Mycophenolate Alkem 250 mg kapsules in die oggend en ses kapsules in die aand
OF
Drie Mycophenolate Alkem 500 mg tablette in die oggend en drie in die aand.
Kinders: Mycophenolate Alkem word nie vir gebruik by kinders na hartoorplanting aanbeveel nie.

Leweroorplanting:
Volwassenes: Jy sal jou eerste dosis binne vier dae na jou oorplantingsoperasie ontvang. Die aanbevole dosis is ses Mycophenolate Alkem 250 mg kapsules in die oggend en ses kapsules in die aand
OF
Drie Mycophenolate Alkem 500 mg tablette in die oggend en drie in die aand.
Kinders: Mycophenolate Alkem word nie vir kinders na leweroorplanting aanbeveel nie.
Dit is baie belangrik dat jy die volle kursus soos wat deur jou dokter voorgeskryf is, voltooi.

Indien jy meer Mycophenolate Alkem geneem het as wat jy behoort:
In die geval van 'n oordosis, kontak jou dokter of apteker onmiddellik. Indien nie een van hulle beskikbaar is nie, verkry hulp by die naaste hospitaal of gifsentrum. Neem hierdie inligtingsblad en enige oorblywende kapsules of tablette saam met jou, sodat die dokter kan weet wat jy geneem het.

Indien jy vergeet om jou Mycophenolate Alkem te neem:
Indien jy 'n dosis oorgeslaan het, neem dit so gou as wat jy onthou. Indien dit amper tyd is vir jou volgende dosis, slaan die dosis oor wat jy gemis het en gaan voort om die kapsule(s) of tablet(te) op die gewone tyd te neem.
Moenie 'n groter of dubbele dosis neem om te vergoed vir die vergete individuele dosisse nie.

5. MOONTLIKE NEWE-EFFEKTE:
Mycophenolate Alkem mag newe-effekte of ongewenste effekte veroorsaak.
Nie al die newe-effekte wat vir Mycophenolate Alkem aangemeld is, is in hierdie inligtingsblad ingesluit nie.

Indien jou algemene gesondheid verswak terwyl Mycophenolate Alkem geneem word, konsulteer asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker.
Hou op om Mycophenolate Alkem te neem en verkry onmiddellik noodbehandeling, indien enige van die volgende newe-effekte voorkom:
- Vinnige of onreëlmatige asemhaling en/of hartklop
- Swelsels soos jeukbulte op die gesig, ooglede, mond, lippe of tong
- Kortasemheid of probleme om asem te haal

Hierdie is alles baie ernstige newe-effekte. Jy mag 'n allergiese reaksie vir Mycophenolate Alkem hê en benodig dringende mediese aandag.
Sê dadelik vir jou dokter indien jy enige van die volgende newe-effekte ervaar, wat dikwels mag voorkom (gelys met die baie ernstige / lewensbedreigende newe-effekte eerste, en in volgorde van afnemende ernstigheidsgraad daarna):
- Tekens van bloedstoornisse, soos oormatige moegheid, duiseligheid, onverklaarde bloeding, kneusing of bleekheid
- Hoë of lae bloeddruk
- Hoë vlakke van cholesterol (vet) in jou bloed (wat deur jou dokter met 'n bloedcholesteroltoets bepaal word)
- Diabetes (gekenmerk deur gereelde urinering, oormatige dors, ongewone moegheid)
- Lae kaliumvlakke in jou bloed (gekenmerk deur braking, naarheid, hardlywigheid, lae bloeddruk) of abnormale hoë kaliumvlakke in jou bloed (gekenmerk deur naarheid, ongewone swakheid of moegheid, spierswakheid)
- Abnormale lae vlakke van magnesium in jou bloed (gekenmerk deur swakheid, spierkrampe of onreëlmatige hartklop)
- Abnormale lae vlakke natrium (sout) in jou bloed (gekenmerk deur naarheid en braking, hoofpyn, verwarring, ongewone swakheid of moegheid, aptytverlies, rusteloosheid, prikkelbaarheid, spierswakheid, spasmas of krampe)
- Abnormale lae vlakke fosfaat in jou bloed (gekenmerk deur spierwanfunksie en -swakheid, prikkelbaarheid of verwarring)
- Senuweeagtige opgewondenheid, angstigheid, verwarring, depressie
- Bloed in jou urine
- Blaasinfeksie (gekenmerk deur 'n brandgevoel wanneer jy urineer), probleme om te urineer, wit skuim in jou urine, intense pyn in die gebied tussen jou heupe en ribbes
- Longontsteking (inflammasie van die longe, veroorsaak deur 'n bakteriële of virusinfeksie, gekenmerk deur hoes, koors, bewe, kortasemheid of steekpyn in die borskas met diep asemteue)
- Sepsis (bakteriële infeksie in jou bloedstroom of liggaamsweefsel, gekenmerk deur koors, lae liggaamstemperatuur en vinnige asemhaling)
- Duiseligheid, probleme om te slaap, hande of voete wat bewe of ruk
- Swelling van onderbene of voete
- Diarree, naarheid, braking, hardlywigheid, sooibrand
- Ongewone swakheid of moegheid, koors, hoofpyn, maagpyn, rugpyn, borskaspyn
- Hooikoors

Sê dadelik vir jou dokter indien jy enige van die volgende newe-effekte ervaar, wat minder dikwels mag voorkom (gelys met die baie ernstige / lewensbedreigende newe-effekte eerste, en in volgorde van afnemende ernstigheidsgraad daarna):
- Verkleuring van die vel weens bloedstoornisse
- Onderaktiewe skildklier (gekenmerk deur massatoename, ongewone swakheid en depressie) of ooraktiewe skildklier (gekenmerk deur prikkelbaarheid, vinnige onreëlmatige hartklop, toename in sweetafskeiding en massaverlies)
- Cushing se sindroom (hoë vlakke kortisol, gekenmerk deur sentrale vetsug, 'n ronde gesig, vermeerdering van vet om die nek en arms en bene wat dunner word)
- Toevalle (konvulsies), gemoedsveranderings, sien of hoor goed wat nie bestaan nie, senuweeskade (gekenmerk deur spierswakheid, krampe en spasmas of prikkelende sensasie, gevoelloosheid en pyn), abnormale denke, 'n abnormale toename in sensitiwiteit vir stimuli van jou sintuie, verloor kontak met realiteit
- Asidose (te veel suur in jou liggaam, volgens 'n urientoets wat deur jou dokter uitgevoer is om jou liggaam se pH-vlakke te kontroleer), dehidrasie (wanneer jou liggaam meer vloeistof verloor as wat dit inneem), massatoename
- Verhoogde spierspanning
- Tintelende, brandende, prikkelende of gevoellose sensasie van die vel ("naalde en spelde"), slaperigheid
- Visiestoornisse, ooginfeksie, katarak (vertroebeling van die oog)
- Gehoorverlies
- Versteurings van jou hartritme, hartsteurings, hartversaking, abnormale stadige of vinnige hartritme
- Lighoofdigheid wanneer jy opstaan uit 'n sittende posisie of wanneer jy gelê het
- Asma, longversteurings (gekenmerk deur moeite om asem te haal, hoes bloed (gewoonlik pienk, skuimerige sputum), oormatige sweetafskeiding, angstigheid, bleek vel, griepagtige simptome, borskaspyn)
- Bloed in jou stoelgange, swaminfeksie in jou mond, ontsteking van die tandvleise, mond, slukderm of pankreas, oorgroei van weefsel van die tandvleis
- Velkankers
- Lewersiekte (gekenmerk deur geel verkleuring van die vel en oë)
- Pynlike of moeilike urinering, behoefte om meer dikwels as gewoonlik te urineer, verlies van blaasbeheer, vervaardig abnormaal min urine, oormatige urinering snags
- Voel 'n abnormale knop onder die vel, vergrote buik, swelling van die gesig, griepagtige simptome, ongewone swakheid of moegheid, sien of voel 'n uitbulting in die omgewing van die maag, gevoel van drukking op die maag
- Beenkrampe, spierpyn, gewrigspyn, abnormale swakheid van sekere spiere
- Aknee, tydelike haarverlies, veluitslag, velinfeksie
- Loopneus, seer keel

Indien enige van hierdie newe-effekte voortduur of erger word, lig asseblief jou dokter of professionele gesondheidsorgwerker so gou as moontlik in.

6. BERGING EN WEGDOENING VAN Mycophenolate Alkem:
Bêre by of onder 25 °C.
Beskerm teen lig en vog.
Hou die stulpstroke in die buitenste karton tot benodig vir gebruik.
HOU ALLE MEDISYNES BUITE DIE BEREIK EN SIG VAN KINDERS.
Moenie gebruik na die vervaldatum wat op die karton gedruk is nie.
Neem alle ongebruikte medisyne terug na jou apteker.

7. AANBIEDING VAN Mycophenolate Alkem:
Mycophenolate Alkem 250 mg word verpak in gewone aluminiumfoelie / wit ondeursigtige PVC stulpstroke wat 10 kapsules bevat. 10 stulpstroke met 10 kapsules elk word in 'n buitenste karton verpak.
Mycophenolate Alkem 500 mg word verpak in gewone aluminiumfoelie / wit ondeursigtige PVC stulpstroke wat 10 tablette bevat. 5 stulpstroke met 10 tablette elk word in 'n buitenste karton verpak.

8. IDENTIFIKASIE VAN Mycophenolate Alkem:
Mycophenolate Alkem 250 mg (kapsules): Grootte "1" kapsule met 'n blou doppie en 'n bruin romp met "266" in swart ink op die romp gedruk.
Mycophenolate Alkem 500 mg (tablette): Ligpers, kapletvormige, bikonvekse, filmbedekte tablet, met "265" aan die een kant ingepers en glad aan die ander kant.

9. REGISTRASIENOMMERS:
Mycophenolate Alkem 250 mg: 45/32.2/0219
Mycophenolate Alkem 500 mg: 45/32.2/0220

10. NAAM EN ADRES VAN DIE REGISTRASIEHOUER:
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11. DATUM VAN PUBLIKASIE:
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PT 2320