Concord Biotech Limited 297-298/2P, Valthera, Tal. Dholka, Dist. Ahmedabad - 382 225									
Artwork Approval: Medication Guide									
Product:	roduct: Printed medication guide for Mycophenolate Mofetil Tablets, USP 500 mg. Market: US Size: 470 x 220 Artwork Supersede: NA								NA
Item code:	VP00389-00	Mfg. Location:	Valthera	Component		Med	Medication Guide		NA
Substrate: 28 gsm bible paper printed Medication guide for Mycophenolate Mofetil Tablets, USP 500 mg									
Reason for Issuance: NA									

220.00 mm mycophenolate mofetil may cause an infection of the brain **MEDICATION GUIDE** that may cause death. You are at risk for this brain Mycophenolate Mofetil Tablets, USP 500 mg infection because you have a weakened immune (MYE koe FEN oh late MOE fe til) system. Call your doctor right away if you have any of the following symptoms: Read the Medication Guide that comes with Mycophenolate • weakness on one side of the body mofetil tablets before you start taking it and each time you refill • you do not care about things that you usually care about your prescription. There may be new information. This (apathy) Medication Guide does not take the place of talking with your • you are confused or have problems thinking doctor about your medical condition or treatment. you can not control your muscles What is the most important information I should know • Fungal infections. Yeasts and other types of fungal about mycophenolate mofetil tablets? infections can happen with mycophenolate mofetil Mycophenolate mofetil tablets can cause serious side and can cause serious tissue and blood effects, including: infections (see "What are the possible side effects of Increased risk of loss of a pregnancy (miscarriage) and mycophenolate mofetil tablets?"). higher risk of birth defects. Females who take mycophenolate Call your doctor right away if you have any of the following mofetil during pregnancy have a higher risk of miscarriage signs and symptoms of infection: during the first 3 months (first trimester), and a higher risk that • temperature of 100.5°F or greater their baby will be born with birth defects. • pain during urination • If you are a female who can become pregnant, your cold symptoms, such as a runny nose or sore throat doctor must talk with you about acceptable birth control white patches in the mouth or throat methods (contraceptive counseling) to use while taking • flu symptoms, such as an upset stomach, stomach pain, mycophenolate mofetil tablets. You should have 1 vomiting or diarrhea pregnancy test immediately before starting mycophenolate unexpected bruising or bleeding mofetil tablets and another pregnancy test 8 to 10 days • earache or headache later. Pregnancy tests should be repeated during routine cuts, scrapes or incisions that are red, warm and oozing pus follow-up visits with your doctor. Talk to your doctor about the results of all of your pregnancy tests. See "What are the possible side effects of mycophenolate You must use acceptable birth control during your entire mofetil tablets?" for information about other serious side mycophenolate mofetil treatment and for effects. 6 weeks after stopping mycophenolate mofetil, unless at any time you choose to avoid sexual intercourse (abstinence) What is mycophenolate mofetil tablets? with a man completely. Mycophenolate mofetil decreases Mycophenolate mofetil tablets is a prescription medicine to blood levels of the hormones in birth control pills that you prevent rejection (antirejection medicine) in people who take by mouth. Birth control pills may not work as well while have received a kidney, heart or liver transplant. Rejection is you take mycophenolate mofetil tablets, and you could when the body's immune system perceives the new organ as become pregnant. If you take birth control pills while using a "foreign" threat and attacks it. mycophenolate mofetil tablets you must also use Mycophenolate mofetil tablets is used with other medicines another form of birth control. Talk to your doctor about containing cyclosporine and corticosteroids. other birth control methods that you can use while taking mycophenolate mofetil. Who should not take mycophenolate mofetil tablets? If you are sexually active male whose female partner can Do not take mycophenolate mofetil tablets if you are allergic become pregnant while you are taking mycophenolate

to mycophenolate mofetil or any of the ingredients in mofetil tablets, use effective contraception during mycophenolate mofetil tablets. See the end of this treatment and for at least 90 days after stopping Medication Guide for a complete list of ingredients in

- mycophenolate mofetil tablets. mycophenolate mofetil tablets. If you plan to become pregnant, talk with your doctor. Your doctor will decide if other medicines to prevent rejection may be right for you. mofetil tablets? If you become pregnant while taking mycophenolate mofetil, do not stop taking including if you: mycophenolate mofetil tablets. Call your doctor right • have any digestive problems, such as ulcers. away. You and your doctor may decide that other medicines to prevent rejection may be right for you. You and your doctor should report your pregnancy to the Mycophenolate Pregnancy Registry either: • By phone at 1-800-617-8191 or these disorders. By visiting the REMS website at www.mycophenolateREMS.com The purpose of this registry is to gather information about the health of you and your baby. Increased risk of getting certain cancers. People who take Mycophenolate mofetil have a higher risk of getting mycophenolate mofetil tablets?" lymphoma, and other cancers, especially skin cancer. Tell your doctor if you have: • unexplained fever, prolonged tiredness, weight loss or lymph node swelling • a brown or black skin lesion with uneven borders, or one part of the lesion does not look like the other • a change in the size and color of a mole • a new skin lesion or bump any other changes to your health mofetil may affect how some medicines work. Increased risk of getting serious infections. Especially tell your doctor if you take: Mycophenolate mofetil weakens the body's immune system and affects your ability to fight infections. Serious infections can happen with mycophenolate mofetil tablets mycophenolate mofetil tablets?" and can lead to hospitalizations and death. These serious infections can include: • Viral infections. Certain viruses can live in your body and mofetil tablets. cause active infections when your immune system is weak. Viral infections that can happen with mycophenolate mofetil include: • Shingles, other herpes infections, and cytomegalovirus (CMV). CMV can cause serious tissue and blood infections. should not be taken at the same time). • BK virus. BK virus can affect how your kidney works and cause your transplanted kidney to fail. • Hepatitis B and C viruses. Hepatitis viruses can affect BACTRIM Ds[™]). how your liver works. Talk to your doctor about how hepatitis viruses may affect you. A brain infection called Progressive Multifocal Leukoencephalopathy (PML). In some patients,
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Prepared By	Reviewed By	Reviewed By	Reviewed By	Reviewed By	Approved By	
Pack F&D	F&D	RA	Production	QC	QA	

What should I tell my doctor before taking mycophenolate

Tell your doctor about all of your medical conditions,

- have Lesch-Nyhan syndrome, Kelley-Seegmiller syndrome, or another rare inherited deficiency hypoxanthineguanine phosphoribosyl-transferase (HGPRT). You should not take mycophenolate mofetil tablets if you have one of
- plan to receive any vaccines. People taking mycophenolate mofetil tablets should not receive live vaccines. Some vaccines may not work as well during treatment with mycophenolate mofetil tablets.
- are pregnant or plan to become pregnant. See "What is the most important information I should know about
- are breastfeeding or plan to breastfeed. It is not known if mycophenolate mofetil passes into breast milk. You and your doctor will decide if you will take mycophenolate mofetil tablets or breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Some medicines may affect the way mycophenolate mofetil works, and mycophenolate

- birth control pills (oral contraceptives). See "What is the most important information I should know about
- sevelamer (Renagel[®], Renvela[™]). These products should be taken at least 2 hours after taking mycophenolate
- acyclovir (Zovirax[®]), valacyclovir (Valtrex[®]), ganciclovir (CYTOVENE[®]-IV, Vitrasert[®]), valganciclovir (VALCYTE[®]).
- rifampin (Rifater[®], Rifamate[®], Rimactane[®], Rifadin[®]).
- antacids that contain magnesium and aluminum (mycophenolate mofetil tablets and the antacid
- proton pump inhibitors (PPIs) (Prevacid[®], Protonix[®]).
- sulfamethoxazole/trimethoprim (BACTRIM[™],
- norfloxacin (Noroxin[®]) and metronidazole (Flagyl[®], Flagyl[®] ER, Flagyl[®] IV, Metro IV, Helidac[®], Pylera[™]).
- ciprofloxacin (Cipro[®], Cipro[®] XR, Ciloxan[®], Proquin[®] XR) and amoxicillin plus clavulanic acid (Augmentin[®],



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	Augmentin Xr [™]).	area pain or stomach-area pain that does not go away, or if			
	 azathioprine (Azasan[®], Imuran[®]). cholestyramine (Questran Light[®], Questran[®], Locholest 	you have diarrhea.			
	Light, Locholest, Prevalite [®]). Know the medicines you take. Keep a list of them to show to	The most common side effects of mycophenolate mofetil tablets include: • diarrhea			
	your doctor or nurse and pharmacist when you get a new medicine. Do not take any new medicine without talking with your doctor.	blood problems including low white and red blood cell countsinfections			
	How should I take mycophenolate mofetil tablets?Take mycophenolate mofetil tablets exactly as	 blood pressure problems fast heart beat swelling of the lower legs, ankles and feet 			
	 prescribed. Do not stop taking mycophenolate mofetil tablets or change the dose unless your doctor tells you to. If you miss a dose of mycophenolate mofetil tablets, or you 	 changes in laboratory blood levels, including high levels of blood sugar (hyperglycemia) stomach problems including diarrhea, constipation, nausea 			
	are not sure when you took your last dose, take your prescribed dose of mycophenolate mofetil tablets as soon as you remember. If your next dose is less than 2 hours away, skip the missed dose and take your next dose at your	 and vomiting rash nervous system problems such as headache, dizziness and tremor 			
	normal scheduled time. Do not take 2 doses at the same time. Call your doctor if you are not sure what to do.Take mycophenolate mofetil tablets on an empty stomach,	 Side effects that happen more often in children than in adults taking mycophenolate mofetil tablets include: stomach area pain 			
	 unless your doctor tells you otherwise. Do not crush mycophenolate mofetil tablets. If you are not able to swallow mycophenolate mofetil 	feverinfectionpain			
	tablets, your doctor may prescribe mycophenolate mofetil Oral Suspension. This is a liquid form of mycophenolate mofetil. Your pharmacist will mix the medicine before you	 blood infection (sepsis) diarrhea vomiting 			
	 pick it up from a pharmacy. If you take too much mycophenolate mofetil tablets, call your doctor or the poison control center right away. 	 sore throat colds (respiratory tract infections) high blood pressure 			
	What should I avoid while taking mycophenolate mofetil tablets?	 low white blood cell count low red blood cell count			
	 Avoid becoming pregnant. See "What is the most important information I should know about mycophenolate mofetil tablets?" 	These are not all of the possible side effects of mycophenolate mofetil tablets. Tell your doctor about any side effect that bothers you or that does not go away.			
	• Limit the amount of time you spend in sunlight. Avoid using tanning beds or sunlamps. People who take mycophenolate mofetil tablets have a higher risk of	Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Concord Biotech Limited			
	getting skin cancer (See "What is the most important information I should know about mycophenolate mofetil tablets?"). Wear protective clothing when you	at Telephone : 1-844-553-5534, Fax : 1-844-552-5515.			
mm	are in the sun and use a broad-spectrum sunscreen with a high protection factor. This is especially important if your skin is very fair or if you have a family history of skin cancer.	 How should I store mycophenolate mofetil tablets? Store mycophenolate mofetil tablets at room temperature, between 59°F to 86°F (15°C to 30°C). Koop Mycophenolate mofetil tablets in the light resistant. 			

• You should not donate blood while taking mycophenolate

mofetil tablets and for at least 6 weeks after stopping mycophenolate mofetil tablets.

- You should not donate sperm while taking mycophenolate mofetil tablets and for 90 days after stopping mycophenolate mofetil tablets.
- Mycophenolate mofetil tablets may influence your ability to drive and use machines (See "What are the possible side effects of mycophenolate mofetil tablets?"). If you experience drowsiness, confusion, dizziness, tremor, or low blood pressure during treatment with mycophenolate mofetil tablets, you should be cautious about driving or using heavy machines.

What are the possible side effects of mycophenolate mofetil tablets?

Mycophenolate mofetil tablets can cause serious side effects, including:

- See "What is the most important information I should know about mycophenolate mofetil tablets?"
- Low blood cell counts. People taking high doses of mycophenolate mofetil tablets each day may have a decrease in blood counts, including:
 - white blood cells, especially neutrophils. Neutrophils fight against bacterial infections. You have a higher chance of getting an infection when your white blood cell count is low. This is most common from 1 month to 6 months after your transplant.
 - red blood cells. Red blood cells carry oxygen to your body tissues. You have a higher chance of getting severe anemia when your red blood cell count is low.
 - platelets. Platelets help with blood clotting.

Your doctor will do blood tests before you start taking mycophenolate mofetil tablets and during treatment with mycophenolate mofetil tablets to check your blood cell counts. Tell your doctor right away if you have any signs of infection (see "What is the most important information I should know about mycophenolate mofetil tablets?"), including any unexpected bruising or bleeding. Also, tell your doctor if you have unusual tiredness, lack of energy, dizziness or fainting.

• **Stomach problems.** Stomach problems including intestinal bleeding, a tear in your intestinal wall (perforation) or stomach ulcers can happen in people who take mycophenolate mofetil tablets. Bleeding can be severe and you may have to be hospitalized for treatment. Call your doctor right away if you have sudden or severe stomach-

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container that it comes in.

Keep mycophenolate mofetil tablets and all medicines out of the reach of children.

General Information about the safe and effective use of mycophenolate mofetil tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use mycophenolate mofetil tablets for a condition for which it was not prescribed. Do not give mycophenolate mofetil tablets to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about mycophenolate mofetil tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about mycophenolate mofetil tablets that is written for health professionals.

What are the ingredients in mycophenolate mofetil tablets? Active Ingredient: mycophenolate mofetil Inactive Ingredients:

Microcrystalline cellulose, Povidone, Croscarmellose sodium and Magnesium stearate.

The film coating contains Hypromellose , Titanium dioxide, Polyethylene glycol, Iron oxide red, FD&C blue#2 aluminium lake and black iron oxide.

Manufactured By:

Concord Biotech Limited, 297-298/2P, At Valthera, Ta. Dholka, Ahmedabad – 382225, Gujarat, India.

Distributed by:

Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202 United States

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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