NO ACTIVATION REQUIRED

ONE TIME ONLY

FREE 30-DAY SUPPLY VOUCHER

BIN#	600426	GRP#	EV66008002
PCN#	54	MEM ID#	**49945972725**

Eligible patients may receive one free* 30-day supply of Myhibbin

Myhibbin™
(mycophenolate mofetil oral suspension)

* Subject to Terms and Conditions below

Patients who have been prescribed MyhibbinTM (mycophenolate mofetil oral suspension), for an approved use consistent with FDA-approved product labeling, may be eligible to receive one FREE 30-Day supply voucher, which will allow them to start their treatment quickly. See below for Terms and Conditions of this program.

Myhibbin™
(mycophenolate mofetil oral suspension)

Terms and Conditions:

This voucher is good for all eligible patients who are residents of the United States or Puerto Rico and have a valid Myhibbin prescription written within the last 30 days. This free 30-day voucher is not health insurance. Void where prohibited by law. No claim for reimbursement for product dispensed pursuant to this voucher may be submitted to any third party payer, whether a commercial, private or a government payer. Voucher is limited to one per patient and is not transferable. Not valid if reproduced. Prescriber ID# required on prescription. This free 30-day voucher cannot be combined with any other rebate/offer, free trial or similar offer for the specified prescription.

Patient Instructions:

This free 30-day voucher is valid for up to a 30 day free prescription of Myhibbin (mycophenolate mofetil oral suspension). Voucher must be presented to your pharmacist along with a valid prescription. One offer per patient per lifetime. Consumers with questions, please call 1-877-809-1342.

Pharmacist Instructions:

The free 30-day voucher must accompany a valid prescription. Voucher only applicable for a 30-day free prescription. One offer per patient per lifetime No substitution allowed. Please dispense at no cost to the patient. For reimbursement, please submit this electronically as a primary claim to CHANGE HEALTHCARE. Do not submit to any other payer. The information printed on the card (or reverse side) should be used when submitting for reimbursement. For questions, please call the Help Desk at 1-800-433-4893.

Azurity and its service providers reserve the right to rescind, recall, revoke or amend this offer without notice at any time.

Please see second page for Important Safety Information and Myhibbin.com for complete Prescribing Information.

IMPORTANT SAFETY INFORMATION

INDICATION

MYHIBBIN™ (mycophenolate mofetil oral suspension) is an antimetabolite immunosuppressant indicated for the prophylaxis of organ rejection in adult and pediatric recipients 3 months of age and older of allogeneic kidney, heart, or liver transplants, in combination with other immunosuppressants.

WARNING: EMBRYOFETAL TOXICITY, MALIGNANCIES, and SERIOUS INFECTIONS

- **Use during pregnancy is associated with increased risks of first trimester pregnancy loss and congenital malformations. Avoid if safer treatment options are available. Females of reproductive potential must be counseled regarding pregnancy prevention and planning *[see Warnings and Precautions (5.1), Use in Special Populations (8.1, 8.3)]*.**
- **Increased risk of development of lymphoma and other malignancies, particularly of the skin *[see Warnings and Precautions (5.2)]*.**
- **Increased susceptibility to bacterial, viral, fungal, and protozoal infections, including opportunistic infections and viral reactivation of hepatitis B and C, which may lead to hospitalizations and fatal outcomes *[see Warnings and Precautions (5.3)]*.**

Handling and Disposal: Mycophenolate mofetil (MMF) has demonstrated teratogenic effects in humans. Wearing disposable gloves is recommended when wiping the outer surface of the bottle and or the bottle cap. Avoid direct contact of MYHIBBIN with skin or mucous membranes. Follow applicable special handling and disposal procedures according to OSHA Hazardous Drugs. Do not use after 60 days of first opening the bottle.

ADDITIONAL IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Hypersensitivity to mycophenolate mofetil, mycophenolic acid, polysorbate 80, or any other component of the drug product.

WARNINGS AND PRECAUTIONS

Embryofetal Toxicity

Use of MMF during pregnancy is associated with an increased risk of first trimester pregnancy loss and an increased risk of congenital malformations, especially external ear and other facial abnormalities including cleft lip and palate, and anomalies of the distal limbs, heart, esophagus, kidney, and nervous system. Females of reproductive potential must be made aware of these risks and must be counseled regarding pregnancy prevention and planning. Avoid use of MYHIBBIN during pregnancy if safer treatment options are available.

Lymphoma and Other Malignancies

Patients receiving immunosuppressants, including MYHIBBIN, are at increased risk of developing lymphomas and other malignancies, particularly of the skin. The risk appears to be related to the intensity and duration of immunosuppression rather than to the use of any specific agent. For patients with increased risk for skin cancer, exposure to sunlight and UV light should be limited by wearing protective clothing and using a broad-spectrum sunscreen with a high protection factor.

Post-transplant lymphoproliferative disorder (PTLD) developed in 0.4% to 1% of patients receiving MMF (2 g or 3 g) with other immunosuppressive agents in controlled clinical trials of kidney, heart, and liver transplant patients. The majority of PTLD cases appear to be related to Epstein-Barr Virus (EBV) infection. The risk of PTLD appears greatest in those individuals who are EBV seronegative, a population which includes many young children. In pediatric patients, no other malignancies besides PTLD were observed in clinical trials.

Serious Infections

Patients receiving immunosuppressants, including MYHIBBIN, are at increased risk of developing bacterial, fungal, protozoal, and new or reactivated viral infections, including opportunistic infections. The risk increases with the total immunosuppressive load. These infections may lead to serious outcomes,including hospitalizations and death.

Consider dose reduction or discontinuation of MYHIBBIN in patients who develop new infections or reactivate viral infections, weighing the risk that reduced immunosuppression represents to the functioning allograft.

Blood Dyscrasias: Neutropenia and Pure Red Cell Aplasia (PRCA)

Severe neutropenia [absolute neutrophil count (ANC) $<0.5 \times 10^3/\mu L$] developed in transplant patients receiving MMF 3 g daily. Patients receiving MYHIBBIN should be monitored for neutropenia. Neutropenia has been observed most frequently in the period from 31 to 180 days post-transplant in patients treated for prevention of kidney, heart,and liver rejection. The development of neutropenia may be related to MYHIBBIN itself, concomitant medications, viral infections, or a combination of these causes. If neutropenia develops (ANC $<1.3 \times 10^3/\mu L$), dosing with MYHIBBIN should be interrupted or the dose reduced, appropriate diagnostic tests performed, and the patient managed appropriately.

Consider monitoring with complete blood counts weekly for the first month, twice monthly for the second and third months, and monthly for the remainder of the first year.

Gastrointestinal Complications

Gastrointestinal bleeding requiring hospitalization, ulceration, and perforations were observed in clinical trials. Physicians should be aware of these serious adverse effects particularly when administering MYHIBBIN to patients with a gastrointestinal disease.

Patients With Hypoxanthine-Guanine Phosphoribosyltransferase (HGPRT) Deficiency

Mycophenolate mofetil is an inosine monophosphate dehydrogenase (IMPDH) inhibitor; therefore, it should be avoided in patients with hereditary deficiencies of HGPRT, such as Lesch-Nyhan and Kelley-Seegmiller syndromes, because it may cause an exacerbation of disease symptoms characterizedby the overproduction and accumulation of uric acid leading to symptoms associated with gout, such as acute arthritis, tophi, nephrolithiasis or urolithiasis, and renal disease including renal failure.

Acute Inflammatory Syndrome Associated With Mycophenolate Products

Acute inflammatory syndrome (AIS) has been reported with the use of MMF and mycophenolate products, and some cases have resulted in hospitalization. AIS is a paradoxical pro-inflammatory reaction characterized by fever, arthralgias, arthritis, muscle pain, and elevated inflammatory markers, including C-reactive protein and erythrocyte sedimentation rate, without evidence of infection or underlying disease recurrence. Symptoms occur within weeks to months of initiation of treatment or a dose increase. After discontinuation, improvement of symptoms and inflammatory markers are usually observed within 24 to 48 hours.

Monitor patients for symptoms and laboratory parameters of AIS when starting treatment with mycophenolate products or when increasing the dosage. Discontinue treatment and consider other treatment alternatives based on the risk and benefit for the patient.

Immunizations

During treatment with MYHIBBIN, the use of live attenuated vaccines should be avoided (e.g., intranasal influenza, measles, mumps, rubella, oral polio, BCG, yellow fever, varicella, and TY21a typhoid vaccines) and patients should be advised that vaccinations may be less effective. Advise patients to discuss with a physician before seeking any immunizations.

Blood Donation

Patients should not donate blood during therapy and for at least 6 weeks following discontinuation of MYHIBBIN because their blood or blood products might be administered to a female of reproductive potential or a pregnant woman.

Semen Donation

Based on animal data, men should not donate semen during therapy and for 90 days following discontinuation of MYHIBBIN.

Effect of Concomitant Medications on Mycophenolic Acid Concentrations

A variety of drugs have the potential to alter systemic MPA exposure when co-administered with MYHIBBIN. Therefore, determination of MPA concentrations in plasma before and after making any changes to immunosuppressive therapy, or when adding or discontinuing concomitant medications, may be appropriate to ensure MPA concentrations remain stable.

Potential Impairment of Ability to Drive or Operate Machinery

MYHIBBIN may impact the ability to drive and use machines. Patients should avoid driving or using machines if they experience somnolence, confusion, dizziness, tremors, or hypotension during treatment with MYHIBBIN.

ADVERSE REACTIONS

The most common adverse reactions in clinical trials (≥20%) include diarrhea, leukopenia, infection, and vomiting, and there is evidence of a higher frequency of certain types of infections (e.g., opportunistic infection).

DRUG INTERACTIONS

See full prescribing information for drugs that may interfere with systemic exposure and reduce MYHIBBIN efficacy: antacids with magnesium or aluminum hydroxide, proton pump inhibitors, drugs that interfere with enterohepatic recirculation, telmisartan, calcium-free phosphate binders.

MYHIBBIN may reduce the effectiveness of oral contraceptives. Use of additional barrier contraceptive methods is recommended.

See full prescribing information for other important drug interactions.

USE IN SPECIFIC POPULATIONS

Pregnancy

Use of MMF during pregnancy is associated with an increased risk of first trimester pregnancy loss and an increased risk of multiple congenital malformations in multiple organ systems *(see Human Data)*. Oral administration of mycophenolate to rats and rabbits during the period of organogenesis produced congenital malformations and pregnancy loss at doses less than the recommended clinical dose (0.01 to 0.05 times the recommended clinical doses in kidney and heart transplant patients).

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to mycophenolate during pregnancy and those becoming pregnant within 6 weeks of discontinuing MYHIBBIN treatment. To report a pregnancy or obtain information about the registry, visit the Mycophenolate Pregnancy Registry at www.mycophenolateREMS.com or call 1-800-617-8191.

Females and Males of Reproductive Potential

Females of reproductive potential must be made aware of the increased risk of first trimester pregnancy loss and congenital malformations and must be counseled regarding pregnancy prevention and planning.

Pregnancy Planning

For patients who are considering pregnancy, consider alternative immunosuppressants with less potential for embryofetal toxicity whenever possible. Risks and benefits of MYHIBBIN should be discussed with the patient.

Pregnancy Testing

To prevent unplanned exposure during pregnancy, all females of reproductive potential should have a serum or urine pregnancy test with a sensitivity of at least 25 mIU/mL immediately before starting MYHIBBIN. Another pregnancy test with the same sensitivity should be done 8 to 10 days later. Repeat pregnancy tests should be performed during routine follow-up visits. Results of all pregnancy tests should be discussed with the patient. In the event of a positive pregnancy test, consider alternative immunosuppressants with less potential for embryofetal toxicity whenever possible.

Contraception

Female Patients

Females of reproductive potential taking MYHIBBIN must receive contraceptive counseling and use acceptable contraception. Patients must use acceptable birth control during the entire MYHIBBIN therapy, and for 6 weeks after stopping MYHIBBIN, unless the patient chooses abstinence.

Patients should be aware that MYHIBBIN reduces blood levels of the hormones from the oral contraceptive pill and could theoretically reduce its effectiveness.

Male Patients

Genotoxic effects have been observed in animal studies at exposures exceeding the human therapeutic exposures by approximately 1.25 times. Thus, the risk of genotoxic effects on sperm cells cannot be excluded. Based on this potential risk, sexually active male patients and/or their female partners are recommended to use effective contraception during treatment of the male patient and for at least 90 days after cessation of treatment. Also, based on the potential risk of genotoxic effects, male patients should not donate sperm during treatment with MYHIBBIN and for at least 90 days after cessation of treatment.

The Important Safety Information does not include all the information needed to use MYHIBBIN safely and effectively. Please see the full Prescribing Information for MYHIBBIN.

To Report SUSPECTED ADVERSE REACTIONS, contact Azurity Pharmaceuticals, Inc. at 1-800-461-7449, or FDA at 1-800-FDA-1088 or www.fda.gov/MedWatch.

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azurity pharmaceuticals

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(mycophenolate mofetil
oral suspension)