MEDICATION GUIDE
MYHIBBIN® (my hib in)
(mycophenolate mofetil oral suspension)

Read the Medication Guide that comes with MYHIBBIN before you start taking it and each time you refill your prescription. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment.

What is the most important information I should know about MYHIBBIN?

MYHIBBIN can cause serious side effects, including:

Increased risk of loss of a pregnancy (miscarriage) and higher risk of birth defects. Females who take MYHIBBIN during pregnancy have a higher risk of miscarriage during the first 3 months (first trimester), and a higher risk that their baby will be born with birth defects.

- **If you are a female who can become pregnant**, your healthcare provider must talk with you about acceptable birth control methods (contraceptive counseling) to use while taking MYHIBBIN. You should have 1 pregnancy test immediately before starting MYHIBBIN and another pregnancy test 8 to 10 days later. Pregnancy tests should be repeated during routine follow-up visits with your healthcare provider. Talk to your healthcare provider about the results of all of your pregnancy tests.
  You must use acceptable birth control during your entire MYHIBBIN treatment and for 6 weeks after stopping MYHIBBIN, unless at any time you choose to avoid sexual intercourse (abstinence) with a man completely. MYHIBBIN decreases blood levels of the hormones in birth control pills that you take by mouth. Birth control pills may not work as well while you take MYHIBBIN, and you could become pregnant. If you take birth control pills while using MYHIBBIN you must also use another form of birth control. Talk to your healthcare provider about other birth control methods that you can use while taking MYHIBBIN.
- **If you are a sexually active male whose female partner can become pregnant while you are taking MYHIBBIN**, use effective contraception during treatment and for at least 90 days after stopping MYHIBBIN.
- **If you plan to become pregnant**, talk with your healthcare provider. Your healthcare provider will decide if other medicines to prevent rejection may be right for you.

If you become pregnant while taking MYHIBBIN, **do not stop taking MYHIBBIN. Call your healthcare provider right away.** You and your healthcare provider may decide that other medicines to prevent rejection may be right for you.

Increased risk of getting certain cancers. People who take MYHIBBIN have a higher risk of getting lymphoma, and other cancers, especially skin cancer. Tell your healthcare provider 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

Increased risk of getting serious infections. MYHIBBIN weakens the body's immune system and affects your ability to fight infections. Serious infections can happen with MYHIBBIN and can lead to hospitalizations and death. These serious infections can include:

- **Viral infections.** Certain viruses can live in your body and cause active infections when your immune system is weak. Viral infections that can happen with MYHIBBIN include:
  - Shingles, other herpes infections, and cytomegalovirus (CMV). CMV can cause serious tissue and blood infections.
  - 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 how your liver works. Talk to your healthcare provider about how hepatitis viruses may affect you.
  - COVID-19

- **A brain infection called Progressive Multifocal Leukoencephalopathy (PML).** In some patients, MYHIBBIN may cause an infection of the brain that may cause death. You are at risk for this brain infection because you have a weakened immune system. Call your healthcare provider right away if you have any of the following symptoms:
  - weakness on one side of the body
  - you do not care about things you usually care about (apathy)
  - you are confused or have problems thinking
  - you cannot control your muscles

- **Fungal infections.** Yeasts and other types of fungal infections can happen with MYHIBBIN and can cause serious tissue and blood infections (See **"What are the possible side effects of MYHIBBIN?"**).

Call your healthcare provider right away if you have any of the following signs and symptoms of infection:

- temperature of 100.5°F or greater
- cold symptoms, such as a runny nose or sore throat
- flu symptoms, such as an upset stomach, stomach pain, vomiting or diarrhea
- earache or headache
- pain during urination
- white patches in the mouth or throat
- unexpected bruising or bleeding
- cuts, scrapes or incisions that are red, warm and oozing pus

See **"What are the possible side effects of MYHIBBIN?"** for information about other serious side effects.

What is MYHIBBIN?

- MYHIBBIN is a prescription medicine to prevent rejection (antirejection medicine) in people who have received a kidney, heart or liver transplant. Rejection is when the body's immune system perceives the new organ as a "foreign" threat and attacks it.
- MYHIBBIN is used with other medicines containing cyclosporine and corticosteroids.

Do not take MYHIBBIN if you:

- **have a history of allergic reactions to mycophenolate mofetil or any of the ingredients in MYHIBBIN.** See the end of this Medication Guide for a complete list of ingredients in MYHIBBIN.

Before taking MYHIBBIN tell your healthcare provider about all of your medical conditions, including if you:

- have any digestive problems, such as ulcers.
- have Lesch-Nyhan syndrome, Kelley-Seegmiller syndrome, or another rare inherited deficiency hypoxanthine- guanine phosphoribosyl-transferase (HGPRT). You should not take MYHIBBIN if you have one of these disorders.
- plan to receive any vaccines. People taking MYHIBBIN should not receive live vaccines. Some vaccines may not work as well during treatment with MYHIBBIN.
- are pregnant or plan to become pregnant. See **"What is the most important information I should know about MYHIBBIN?"**
- are breastfeeding or plan to breastfeed. It is not known if MYHIBBIN passes into breast milk. You and your healthcare provider will decide if you will take MYHIBBIN 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 MYHIBBIN works, and MYHIBBIN may affect how some medicines work.

Especially tell your healthcare provider if you take:

- birth control pills (oral contraceptives). See **"What is the most important information I should know about MYHIBBIN?"**
- sevelamer (Renagel, Renvela). These products should be taken at least 2 hours after taking MYHIBBIN.
- acyclovir (Zovirax), valacyclovir (Valtrex), ganciclovir (CYTOVENE-IV, Vitrasert), valganciclovir (VALCYTE).
- rifampin (Rifater, Rifamate, Rimactane, Rifadin).
- antacids that contain magnesium and aluminum (MYHIBBIN and the antacid should not be taken at the same time).
- proton pump inhibitors (PPIs) (Prevacid, Protonix).
- sulfamethoxazole/trimethoprim (BACTRIM, BACTRIM DS).
- 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, Augmentin XR).
- azathioprine (Azasan, Imuran).
- cholestyramine (Questran Light, Questran, Locholest Light, Locholest, Prevalite).

Know the medicines you take. Keep a list of all your medicines. Show them to your healthcare provider or pharmacist when you get a new medicine. Do not take any new medicine without talking with your doctor.

How should I take MYHIBBIN?

- Take MYHIBBIN exactly as prescribed.
- Do not stop taking MYHIBBIN or change the dose unless your healthcare provider tells you to.
- If you miss a dose of MYHIBBIN, or you are not sure when you took your last dose, take your prescribed dose of MYHIBBIN 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 normal scheduled time. Do not take 2 doses at the same time. Call your healthcare provider if you are not sure what to do.
- Take MYHIBBIN on an empty stomach, unless your healthcare provider tells you otherwise.
- **If you are not able to swallow mycophenolate mofetil tablets or capsules, your doctor may prescribe MYHIBBIN. This is a liquid form of mycophenolate mofetil.**
- Do not mix MYHIBBIN with any other medicine. MYHIBBIN should not be mixed with any type of liquids before taking the dose.
- **Do not** let MYHIBBIN come in contact with your skin or mucous membranes.
  - If you accidentally get the oral suspension on the skin, wash the area well with soap and water.
  - If you accidentally get the oral suspension in your eyes or other mucous membranes, rinse with plain water.
- If you take too much MYHIBBIN, call your healthcare provider or the poison control center right away.

What should I avoid while taking MYHIBBIN?

- Avoid becoming pregnant. (See **"What is the most important information I should know about MYHIBBIN?"**)
- Limit the amount of time you spend in sunlight. Avoid using tanning beds or sunlamps. People who take MYHIBBIN have a higher risk of getting skin cancer (See **"What is the most important information I should know about MYHIBBIN?"**). Wear protective clothing when you 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.
- You should not donate blood while taking MYHIBBIN and for at least 6 weeks after stopping MYHIBBIN.
- You should not donate sperm while taking MYHIBBIN and for 90 days after stopping MYHIBBIN.
- MYHIBBIN may influence your ability to drive and use machines (See "**What are the possible side effects of MYHIBBIN?**". If you experience drowsiness, confusion, dizziness, tremor, or low blood pressure during treatment with MYHIBBIN, you should be cautious about driving or using heavy machines.

What are the possible side effects of MYHIBBIN? MYHIBBIN may cause serious side effects, including:

- See **"What is the most important information I should know about MYHIBBIN?"**
- **Low blood cell counts.** People taking high doses of MYHIBBIN 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 healthcare provider will do blood tests before you start taking MYHIBBIN and during treatment with MYHIBBIN to check your blood cell counts. Tell your healthcare provider right away if you have any signs of infection (See **"What is the most important information I should know about MYHIBBIN?"**), 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 MYHIBBIN. 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-area pain or stomach- area pain that does not go away, or if you have diarrhea.
- **Inflammatory reactions.** Some people taking MYHIBBIN may have an inflammatory reaction with fever, joint stiffness, joint pain, and muscle pain. Some of these reactions may require hospitalization. This reaction could happen within weeks to months after your treatment with MYHIBBIN starts or if your dose is increased. Call your healthcare provider right away if you experience these symptoms.
- **Allergic (hypersensitivity) reactions.** Allergic reactions, including a severe allergic reaction called anaphylaxis, can happen after taking MYHIBBIN. Stop taking MYHIBBIN and get emergency medical help right away if you have any of the following symptoms of an allergic reaction:
  - swelling of the face, lips, tongue, or throat
  - rash, hives, or itching
  - fainting, dizziness, feeling lightheaded
  - trouble breathing or swallowing
  - fast heartbeat
  - chest pain

The most common side effects of MYHIBBIN include:

- diarrhea
- blood problems including low white and red blood cell counts
- infections
- blood pressure problems
- fast heartbeat
- swelling of the lower legs, ankles and feet
- changes in laboratory blood levels, including high levels of blood sugar (hyperglycemia)
- stomach problems including diarrhea, constipation, nausea and vomiting
- rash
- nervous system problems such as headache, dizziness and tremor

Side effects that can happen more often in children than in adults taking MYHIBBIN include:

- stomach area pain
- fever
- infection
- pain
- blood infection (sepsis)
- diarrhea
- vomiting
- sore throat
- colds (respiratory tract infections)
- high blood pressure
- low white blood cell count
- low red blood cell count

These are not all of the possible side effects of MYHIBBIN. Tell your doctor about any side effect that bothers you or that does not go away.

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 Azurity Pharmaceuticals, Inc. at 1-800-461-7449.

How should I store MYHIBBIN?

- Store MYHIBBIN at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature]. Do not freeze.
- Wear gloves when wiping the MYHIBBIN bottle and bottle cap.

Keep MYHIBBIN and all medicines out of the reach of children.

General information about the safe and effective use of MYHIBBIN.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use MYHIBBIN for a condition for which it was not prescribed. Do not give MYHIBBIN 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 MYHIBBIN. If you would like more information, talk with your doctor. You can ask your pharmacists or healthcare provider information about MYHIBBIN that is written for health professionals.

What are the ingredients in MYHIBBIN?

Active ingredient: Mycophenolate Mofetil
Inactive ingredients:
MYHIBBIN: dibasic sodium phosphate, glycerin, methylparaben, monobasic sodium phosphate, polysorbate 80, propylparaben, purified water, raspberry flavor, simethicone emulsion, sorbitol solution, and xanthan gum.

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