Myhibbin (mycophenolate mofetil) – New drug approval

- On May 1, 2024, the FDA approved Liqmeds Worldwide's Myhibbin (mycophenolate mofetil) oral suspension, 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.

- Mycophenolate is available in several other formulations for transplant medicine, including as an injection, oral capsule, oral tablet, and oral suspension.

- Myhibbin carries a boxed warning for embryo-fetal toxicity, malignancies, and serious infections.

- Additional warnings and precautions for Myhibbin include blood dyscrasias: neutropenia and pure red cell aplasia; gastrointestinal complications; patients with hypoxanthine-guanine phosphoribosyl-transferase deficiency; acute inflammatory syndrome associated with mycophenolate products; immunizations; blood donation; semen donation; effect of concomitant medications on mycophenolic acid concentrations; and potential impairment of ability to drive or operate machinery.

- The most common adverse reactions (≥ 20%) with Myhibbin use were diarrhea, leukopenia, infection, vomiting, and there is evidence of a higher frequency of certain types of infections eg, opportunistic infection.

- The recommended dose of Myhibbin depends on the population and transplant (see table below).

Population	Dosage
Adults	
Kidney transplant	1 g orally twice daily
Heart transplant	1.5 g orally twice daily
Liver transplant	1.5 g orally twice daily
Pediatrics	
Kidney transplant	600 mg/m^2 orally twice daily, up to maximum of 2 g daily
Heart transplant	600 mg/m^2 orally twice daily (starting dose) up to a maximum of 900 mg/m^2 twice daily (maximum daily dose of 3 g or 15 mL of oral suspension)
Liver transplant	600 mg/m^2 orally twice daily (starting dose) up to a maximum of 900 mg/m^2 twice daily (maximum daily dose of 3 g or 15 mL of oral suspension)

- Liqmeds Worldwide's launch plans for Myhibbin are pending. Myhibbin will be available as a 200 mg/mL oral suspension.