Brand Name: CellCept
Generic: mycophenolate mofetil
Type: small molecule
Year Accepted/Phase: 1995

Mechanism:

Mycophenolate mofetil is a prodrug that is converted to mycophenolic acid (MPA) in the body. MPA inhibits inosine monophosphate dehydrogenase (IMPDH), an enzyme critical for the proliferation of T and B lymphocytes. By inhibiting this enzyme, CellCept reduces the immune response that can lead to organ rejection.

Chemical Structure: N/A

Indication:

CellCept is indicated for the prophylaxis of organ rejection in patients receiving allogeneic kidney, heart, or liver transplants. It is used in combination with other immunosuppressive agents such as cyclosporine and corticosteroids.

Clinical trials:

Kidney Transplant Trials (Phase III)

Purpose: Evaluate the efficacy and safety of mycophenolate mofetil in preventing acute rejection in kidney transplant recipients.
Dates: Results published in the mid-1990s; FDA approval in May 1995.
Results: Mycophenolate mofetil, when used in combination with cyclosporine and corticosteroids, significantly reduced the incidence of acute rejection episodes compared to azathioprine or placebo. This led to the FDA approval of CellCept for kidney transplant recipients.

Heart Transplant Trials (Phase III)

Purpose: Assess the efficacy and safety of mycophenolate mofetil in preventing acute rejection in heart transplant recipients.
Dates: Results published in the late 1990s; FDA approval in December 1997.
Results: Mycophenolate mofetil significantly reduced the incidence of acute rejection episodes and was associated with improved survival rates in heart transplant patients when used in combination with cyclosporine and corticosteroids.

Liver Transplant Trials (Phase III)

Purpose: Evaluate the efficacy and safety of mycophenolate mofetil in preventing acute rejection in liver transplant recipients.
Dates: Results published in the early 2000s; FDA approval in 2003.
Results: Mycophenolate mofetil, in combination with cyclosporine and corticosteroids, showed a significant reduction in the incidence of acute rejection episodes in liver transplant patients, leading to its approval for this indication.

Maintenance Therapy Trials (Phase III)

Purpose: Investigate the long-term efficacy and safety of mycophenolate mofetil as maintenance therapy in kidney transplant recipients.
Dates: Results published in the early 2000s.
Results: Mycophenolate mofetil demonstrated long-term benefits in preventing chronic rejection and improving graft survival, solidifying its role in maintenance immunosuppressive therapy.