



Zortress® (everolimus) – First-time generic

- On March 10, 2020, Hikma launched AB-rated generic versions of Novartis' Zortress (everolimus) 0.25 mg, 0.5 mg and 0.75 mg tablets.
- Zortress is approved for the prophylaxis of organ rejection in kidney and liver transplantation.
- Everolimus is also available as a brand 1 mg tablet (Zortress), brand 10 mg tablet (Afinitor®) and generic 2.5 mg, 5 mg, 7.5 mg tablets, and brand tablet for oral suspension (Afinitor Disperz).
 - Afinitor and generics are approved for hormone receptor-positive, HER2-negative breast cancer, neuroendocrine tumors, renal cell carcinoma, tuberous sclerosis complex (TSC)-associated renal angiomyolipoma, and TSC-associated subependymal giant cell astrocytoma.
 - Afinitor Disperz is approved for TSC-associated subependymal giant cell astrocytoma and TSC-associated partial-onset seizures.
- Zortress carries a boxed warning for malignancies and serious infections, kidney graft thrombosis, nephrotoxicity, and mortality in heart transplantation.



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