Generic Name:
Adalimumab-adaz
Trade Name:
Hyrimoz
Company:
Sandoz
Notes:

Sandoz announced FDA approval of adalimumab-adaz (Hyrimoz), a biosimilar to adalimumab (Humira), for treatment of rheumatoid arthritis, juvenile idiopathic arthritis in patients aged 4 years and older, psoriatic arthritis, ankylosing spondylitis, adult Crohn?s disease, ulcerative colitis, and plaque psoriasis.

The drug, a tumor necrosis factor inhibitor administered subcutaneously by injection, is the third FDA-approved biosimilar to adalimumab.

Approval was based on a randomized, double-blind, three-arm, parallel biosimilarity study that confirmed the pharmacokinetics, immunogenicity, and safety of adalimumab-adaz. The study met the primary endpoint, demonstrating bioequivalence for all primary pharmacokinetic parameters.

A confirmatory efficacy and safety biosimilarity study demonstrated therapeutic equivalence in the sensitive indication of patients with moderate to severe chronic plaque-type psoriasis, with a similar safety and immunogenicity profile to the reference biologic.

The most common adverse reactions (incidence > 10%) were infections (e.g., upper respiratory, sinusitis), injection-site reactions, headache, and rash.
Medication Monitor Categories:
New Drug Approvals