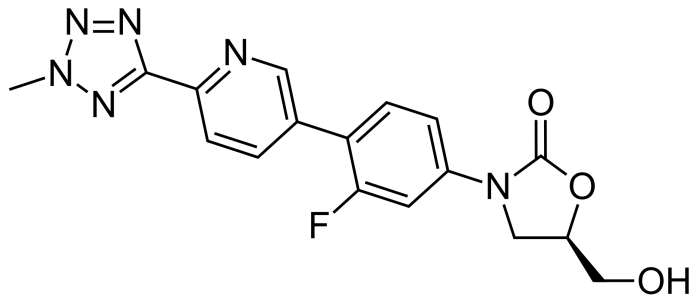
Brand Name: Sivextro
Generic: tedizolid
Type: small molecule
Year Accepted/Phase: 2014

Mechanism:

Tedizolid inhibits bacterial protein synthesis by binding to the 50S ribosomal subunit, preventing the formation of the functional 70S initiation complex, which is essential for bacterial translation processes. This action effectively stops the growth and proliferation of the bacteria.

Chemical Structure:



Indication:

Sivextro is indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following Gram-positive microorganisms:

Staphylococcus aureus (including methicillin-resistant and methicillin-susceptible strains), pyogenes, agalactiae, anginosus group

Enterococcus faecalis

Clinical trials:

ESTABLISH-1 Trial (Phase III)

Pubmed: https://pubmed.ncbi.nlm.nih.gov/23403680/

Purpose: Evaluate the efficacy and safety of tedizolid phosphate compared to linezolid in patients with acute bacterial skin and skin structure infections (ABSSSI).

Dates: Conducted from 2010 to 2012.

Results: The trial demonstrated that a 6-day course of tedizolid was non-inferior to a 10-day course of linezolid in terms of early clinical response at 48-72 hours after the first dose. The primary endpoint was met, and the overall adverse event rates were similar between the two treatments.

Impact: These results supported the use of tedizolid as a shorter-duration therapy for ABSSSI, offering comparable efficacy and safety to the standard 10-day linezolid regimen.

ESTABLISH-2 Trial (Phase III)

Pubmed: https://pubmed.ncbi.nlm.nih.gov/24909499/

Purpose: Confirm the efficacy and safety of tedizolid phosphate versus linezolid in patients with ABSSSI, including a subset of patients with methicillin-resistant Staphylococcus aureus (MRSA) infections.

Dates: Conducted from 2011 to 2013.

Results: The trial found that tedizolid phosphate was non-inferior to linezolid for the primary endpoint of early clinical response at 48-72 hours. The secondary endpoints, including sustained clinical response at the end of treatment and post-therapy evaluation, also supported the non-inferiority of tedizolid. Adverse events were comparable between the treatment groups, with tedizolid showing a slightly better tolerability profile.

Impact: The results reinforced the efficacy and safety profile of tedizolid, leading to its approval as an effective treatment option for ABSSSI, including those caused by MRSA.