

[Home](#) > FDA approves new drug for treatment-resistant forms of pulmonary TB

Generic Name:

Pretomanid

Trade Name:

No trade name

Company:

The Global Alliance for TB Drug Development

Notes:

On August 14, FDA [approved](#) pretomanid tablets in combination with bedaquiline and linezolid for treatment of a specific type of highly treatment-resistant tuberculosis (TB) of the lungs.

Pretomanid in combination with bedaquiline and linezolid is approved for treating a limited and specific population of adult patients with extensively drug resistant, treatment-intolerant or nonresponsive multidrug resistant pulmonary TB. Multidrug-resistant TB and extensively drug-resistant TB are difficult to treat because of resistance to available therapies. According to the World Health Organization, in 2016, there were an estimated 490,000 new cases of multidrug-resistant TB worldwide, with a smaller portion of cases of extensively drug-resistant TB.

The safety and effectiveness of pretomanid, taken orally in combination with bedaquiline and linezolid, was demonstrated primarily in a study of 109 patients with extensively drug-resistant, treatment intolerant or non-responsive multidrug-resistant pulmonary TB. Of the 107 patients who were evaluated 6 months after the end of therapy, 95 (89%) were successes, which significantly exceeded the historical success rates for treatment of extensively drug-resistant TB.

The most common adverse reactions with pretomanid in combination with bedaquiline and linezolid included peripheral neuropathy, acne, anemia, nausea, vomiting, headache, increased liver enzymes, indigestion, rash, increased pancreatic enzymes, visual impairment, hypoglycemia, and diarrhea.

Pretomanid used in combination with bedaquiline and linezolid should not be used in patients with hypersensitivity to bedaquiline or linezolid.

Medication Monitor Categories:

[New Drug Approvals](#)

Source URL: <https://www.aphadruginfoline.com/new-drug-approvals/fda-approves-new-drug-treatment-resistant-forms-pulmonary-tb>