

FDA Approves Berotralstat for Hereditary Angioedema

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FDA recently (December, 2020) approved Berotralstat for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients' ≥ 12 years. It is a plasma kallikrein inhibitor approved as first orally given nonsteroidal agent in HAE at dose of 150mg per day. The data of phase 3 trial of the drug showed that the rate of HAE attack in the patients was when compared with placebo. Moreover, Berotralstat treated patients reported significant reductions in their monthly use of standard of care on-demand medications and overall quality of life. Adverse drug reactions (ADRs) consists QT prolongation, vomiting, diarrhea, back pain, and gastroesophageal reflux disease. There are no data on use in children < 12 years, pregnancy and lactation mothers.

Further reading

https://www.drugs.com/newdrugs/fda-approves-orladeyo-berotralstat-first-oral-once-dailytherapy-prevent-attacks-hereditary5399.html?utm_source=ddc&utm_medium=email&utm_campaign=FDA+Drug+Approval++FDA+Approves+Orladeyo++berotralstat++as+the+First+Oral++Once+Daily+Therapy+to+Prevent+Attacks+in+Hereditary+Angioedema+Patients