Clin Pharmacol Ther. 2020 Apr 17. doi: 10.1002/cpt.1857. [Epub ahead of print]

Clinical Pharmacology Perspectives on the Antiviral Activity of Azithromycin and Use in COVID-19.

Damle B[1], Vourvahis M[1], Wang E[2], Leaney J[3], Corrigan B[4].

Author information

1 Pfizer Global Research and Development, New York, NY, 10017, USA.
2 Pfizer Global Research and Development, 10555 Science Center Dr, San Diego, CA, 92121, USA.
3 Pfizer Global Research and Development, Sandwich, Kent, CT13 9NJ, UK.
4 Pfizer Global Research and Development, 445 Eastern Point Road, Groton, CT, 06340, USA.

Abstract

Azithromycin (AZ) is a broad-spectrum macrolide antibiotic with a long half-life and a large volume of distribution. It is primarily used for the treatment of respiratory, enteric, and genitourinary bacterial infections. AZ is not approved for the treatment of viral infections, and there is no well-controlled, prospective, randomized clinical evidence to support AZ therapy in COVID-19 (Coronavirus Infectious Disease-2019). Nevertheless, there are anecdotal reports that some hospitals have begun to include AZ in combination with hydroxychloroquine (HCQ) or chloroquine (CQ) for treatment of COVID-19. It is essential that the clinical pharmacology (CP) characteristics of AZ be considered in planning and conducting clinical trials of AZ alone or in combination with other agents, to ensure safe study conduct and to increase the probability of achieving definitive answers regarding efficacy of AZ in the treatment of COVID-19. The safety profile of AZ used as an antibacterial agent is well-established.(1) This work assesses published in vitro and clinical evidence for AZ as an agent with antiviral properties. It also provides basic CP information relevant for planning and initiating COVID-19 clinical studies with AZ, summarizes safety data from healthy volunteer studies, and safety and efficacy from Phase 2 and Phase 2/3 studies in patients with uncomplicated malaria, including a Phase 2/3 study in pediatric patients following administration of AZ and CQ in combination. This paper may also serve to facilitate the consideration and use of a priori-defined control groups for future research.

KEYWORDS: Azithromycin; COVID-19; Chloroquine; Coronavirus; Hydroxychloroquine; Pharmacokinetics; SARS-CoV-2; Safety

PMID: 32302411 DOI: 10.1002/cpt.1857