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(54) Title: AZITHROMYCIN DOSAGE FORMS WITH REDUCED SIDE EFFECTS

(57) Abstract: An oral dosage form comprising azithromycin and an effective amount of an alkalizing agent. Preferably, said oral dosage form comprises an effective amount of an alkalizing agent and an azithromycin multiparticulate wherein said multiparticulate comprises azithromycin, a mixture of glyceryl monobehenate, glyceryl dibehenate and glyceryl tribehenate, and a poloxamer. Typically, the oral dosage form includes any suitable oral dosing means such as a powder for oral suspension, a unit dose packet or sachet, a tablet or a capsule.Additionally disclosed is an oral suspension comprising azithromycin, an effective amount of an alkalizing agent and a vehicle. Preferably, the azithromycin is in multiparticulate form wherein said multiparticulate comprises azithromycin, a mixture of glyceryl monobehenate, glyceryl dibehenate and glyceryl tribehenate,and a poloxamer. Also disclosed is a method for reducing gastrointestinal side effects, associated with administering azithromycin to a mammal, comprising contiguously administering azithromycin and an effective amount of alkalizing agent to said mammal wherein the frequency of gastrointestinal side effects is lower than that experienced by administering an equal dose of azithromycin without said alkalizing agent.Further disclosed is a method of treating a bacterial or protozoal infection in a mammal in need thereof comprising contiguously administering to said mammal a single dose of an oral dosage form wherein said oral dosage form comprises azithromycin and an effective amount of an alkalizing agent.Additionally disclosed are azithromycin multiparticulates comprising azithromycin, a surfactant; and a pharmaceutically acceptable carrier.

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