

Consumer Update

Nov 2021

Sulfamethoxazole-Trimethoprim-Hypersensitivity and Other Serious or Fatal Reactions

[EDA performs label update to include the following:](#)

Warnings and Precautions

Hypersensitivity and Other Serious or Fatal Reactions

including severe cutaneous adverse reactions serious adverse reactions Fatalities and , drug reaction lysis, toxic epidermal necroJohnson Syndrome-Stevens(SCARs), including acute febrile neutrophilic dermatosis (DRESS), with eosinophilia and systemic symptoms(AFND), acute generalized erythematous pustulosis (AGEP); fulminant hepatic necrosis; cute and delayed lung injury; agranulocytosis, aplastic anemia and other blood dyscrasias; anaphylaxis and circulatory shock have occurred with the administration of sulfamethoxazole and trimethoprim products, including BACTRIM. Cough, shortness of breath and pulmonary reactions of the respiratory tract have been infiltrates potentially representing hypersensitivity reported in association with sulfamethoxazole and trimethoprim treatment. Other severe pulmonary adverse reactions occurring within days to week of BACTRIM initiation and failure requiring mechanical ventilation or extracorporeal resulting in prolonged respiratorymembrane oxygenation (ECMO), lung transplantation or death have also been reported in patients and otherwise healthy individuals treated with sulfamethoxazole and trimethoprim y shock with fever, severe hypotension, and confusion requiring products. Circulator-intravenous fluid resuscitation and vasopressors has occurred within minutes to hours of rechallenge with sulfamethoxazole and trimethoprim products, including BACTRIM, in patients . ry of recent (days to weeks) exposure to sulfamethoxazole and trimethoprimwith histoBACTRIM should be discontinued at the first appearance of skin rash or any sign of a serious adverse reaction. A skin rash may be followed by more severe reactions, such as Stevens-DRESS, AFND, AGEP, hepatic necrosis or Johnson syndrome, toxic epidermal necrolysis, serious blood disorder.

References: *FDA* ([Click here](#))