



## SAFETY ALERT

DRAP SAFTEY ALERT NO. 64

### Safety Alert of Risk of Circulatory Shock with the Sulfamethoxazole and trimethoprim drug combination

Date: 6<sup>th</sup> of Februry, 2026

#### Target Audience.

- Provincial Health Departments/Provincial PV Centres;
- Manufacturers and importers of Sulfamethoxazole & Trimethoprim combination;
- Healthcare Professionals; and
- Patients.

#### Background.

The PRAC of the EMA in its meeting of 5-8<sup>th</sup> of May, 2025, recommended updating the product information for combination products of sulfamethoxazole and trimethoprim (also called *cotrimoxazole*) to include the risk of circulatory shock. The PRAC recommended that under the undesirable effects section of the Summary of Product Characteristics (SmPC), drug reaction of "Circulatory shock" will be added with the frequency "Not known". It was also informed that cases of circulatory shock, often accompanied by fever and not responding to standard treatment for hypersensitivity, have been reported with the medicine, mainly in immunocompromised patients. Patients should call the emergency department immediately if experiencing multiple symptoms such as fever, very low blood pressure or increased heart rate after taking this drug, as it may be a sign of shock.

#### Action in Pakistan.

The case was again discussed in the 6<sup>th</sup> meeting of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC) held on 31<sup>st</sup> of December, 2025 which decided as per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022 that registration holders are required to include the risk of "circulatory shock", with a frequency of "not-known", in the Adverse Drug Reactions (ADRs) section of the SmPC/label of the sulfamethoxazole-trimethoprim combination, in line with the decision of EMA-PRAC.

#### Therapeutic Good Affected.

**Name:** A combination of Sulfamethoxazole and Trimethoprim is a prescription antibiotic medicine indicated for the treatment of various bacterial infections.





### **Advice for Healthcare Professionals.**

Healthcare professionals are informed that cases of circulatory shock, with a frequency of “*not-known*”, often accompanied by fever and not responding to standard treatment for hypersensitivity, have been reported with the Sulfamethoxazole + Trimethoprim drug combination, mainly in immunocompromised patients. Advise patients to consult a doctor or visit hospitals if they develop symptom of circulatory shock.

### **Advice for patients.**

Patients are advised to immediately consult their doctors or visit a hospital if they experience multiple symptoms such as fever, very low blood pressure or increased heart rate after taking this drug, as it may be a sign of shock.

### **Guidelines for reporting Adverse Drug Reactions (ADRs).**

Healthcare professionals and patients are requested to report any adverse drug reaction with the Sulfamethoxazole & Trimethoprim drug combination and/or any other medicines to the National Pharmacovigilance Centre (NPC), Drug Regulatory Authority of Pakistan (DRAP), through the [Med Vigilance E-Reporting System \(E-forms\)](#) available on the DRAP website. Similarly, adverse events and adverse drug reactions can also be reported through the VigiMobile App by scanning the following QR code, which can also be downloaded (add to home screen) in the mobile:



### **References.**

- [Minutes of the 6<sup>th</sup> meeting of the Pharmacovigilance Risk Assessment Expert Committee \(PRAEC\), DRAP.](#)
- [EMA-PRAC: Minutes for PRAC meeting on 05-08 May 2025.](#)
- [EMA PRAC recommendations on signals Adopted at the 5-8 May 2025 PRAC meeting](#)

