

# SFDA

## Safety Communication

[17/03/2025]

### **Risk of ‘Acute Tubulointerstitial Nephritis (TIN)’ associated with use Proton Pump Inhibitors (PPIs)**

The Saudi Food and Drug Authority (SFDA) would like to notify healthcare professionals about the risk of Acute Tubulointerstitial Nephritis (TIN)’ associated with use Proton Pump Inhibitors (PPIs).

PPIs are a group of medications commonly used to treat various conditions related to excessive stomach acid production. Acute Interstitial Nephritis (AIN), now updated to the term acute tubulointerstitial nephritis (TIN).

TIN has been observed in patients using PPIs and can occur at any stage of treatment. It is characterized by an inflammatory reaction within the tubulointerstitial space of the kidney. Acute TIN can result in acute kidney injury. A delay in diagnosis and continued use of PPIs can impair recovery from the acute kidney injury and may lead to chronic renal failure. Patients may present with varying signs and symptoms from symptomatic hypersensitivity reactions (e.g., fever, rash, or arthralgia), to non-specific symptoms of decreased renal function (e.g., malaise, nausea, or anorexia).

However, the product information will updated to reflect the updated safety information.

**The SFDA provides the following recommendations for healthcare professionals:**

- PPI therapy should be discontinued if TIN is suspected.
- PPIs are contraindicated in individuals who have previously experienced TIN during PPI treatment.
- Patients should be advised to report any reduction in urine volume or signs of blood in their urine while using PPIs.
- Healthcare professionals are strongly encouraged to report any adverse drug reactions (ADRs) to the SFDA.

**For a list of Proton Pump Inhibitors (PPIs) registered in Saudi Arabia, please refer to the [SFDA Drug List](#)**

**Call for reporting:**

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:

The National Pharmacovigilance Centre (NPC):

SFDA Call Center: 19999

E-mail: [npc.drug@sfd.gov.sa](mailto:npc.drug@sfd.gov.sa)

Website: <https://ade.sfda.gov.sa>

aRMM:

