

Consumer Update

Feb 2022

Omeprazole Risk of risk of nephrotoxicity

EDA performs Label Update to include the following:

Warnings

Renal impairment

Acute tubulointerstitial nephritis (TIN) has been observed in patients taking omeprazole and may occur at any point during omeprazole therapy.

Acute tubulointerstitial nephritis can progress to renal failure.

Omeprazole should be discontinued in case of suspected TIN, and appropriate treatment should be promptly initiated.

*** Adverse reactions**

The following adverse reaction(s) should be added or amended under the SOC Renal and urinary disorders with a frequency rare:

Tubulointerstitial nephritis (with possible progression to renal failure)

References: EMA ([Click here](#))