

SFDA

Safety Communication

[1/11/2023]

The Potential Risk of Impotence with the Use of Products Containing Omeprazole.

The Saudi Food and Drug authority (SFDA) would like to notify healthcare professionals about the potential risk of impotence associated with the use of omeprazole containing products.

Omeprazole is a Proton Pump Inhibitor (PPI) that suppresses basal and stimulated gastric acid secretion by inhibiting the parietal cell H⁺/K⁺ ATP pump. It is approved in Saudi Arabia for management of gastroesophageal disease (GERD), peptic ulcer disease (PUD), gastric ulcers, duodenal ulcers, reflux esophagitis, Zollinger-Ellison syndrome

The SFDA reviewed the current evidence including published literature and post-marketing data on the potential risk of impotence with the use of omeprazole containing products. The review included four observational studies that identified several cases suggesting a possible association between omeprazole containing products and impotence. Moreover, the SFDA identified 288 spontaneous case reports of impotence event reported with omeprazole use in the World Health Organization (WHO) database.

Therefore, the SFDA requests to update the product information of omeprazole containing products as following:

Section 4.8: Undesirable Effects:

Reproductive system and breast disorders: Impotence (frequency unknown)

It is noteworthy to mention that erectile dysfunction or impotence adverse event is already included in the product information of other PPIs such as esomeprazole, pantoprazole, lansoprazole, rabeprazole and dexlansoprazole.

For further information on registered omeprazole containing products, please visit the SFDA

[Drug List](#)

Call for reporting:

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

The National Pharmacovigilance Centre (NPC):

Call Center: 19999

E-mail: npc.drug@sfda.gov.sa

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

Risk Minimization Measures:

