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Letter to the Editor

Ranitidine – update on latest FDA actions

Sir,

Ranitidine has maintained a key therapeutic role in managing acid-related disorders due to its favourable efficacy–tolerability profile and consistent pharmacodynamic behaviour.[1] Since its introduction, clinicians have relied on its consistent and sustained suppression of gastric acid secretion, which has translated into effective relief of gastroesophageal reflux symptoms, improved healing of peptic ulcers, and dependable control of episodic acid-related discomfort.[1] Decades of clinical use have generated a robust and reassuring evidence base demonstrating ranitidine's safety and effectiveness across diverse patient populations.[1]

Several attributes have contributed to its continued clinical acceptance. Ranitidine offers a simple way to reduce gastric acid secretion, delivering rapid and dependable relief.[1] This makes it a suitable choice for patients requiring quick, reliable acid suppression.[1] Its safety in elderly patients is well-supported, as studies show no difference in the incidence of adverse events between older and younger individuals receiving ranitidine.[2] Compared with PPIs, ranitidine is associated with fewer clinically significant interactions, partly because it is not a potent inhibitor of cytochrome P450 enzymes—an advantage for patients receiving polypharmacy, including cardiovascular agents and antidiabetic medications.[3,4] Additionally, it offers better nocturnal acid control than omeprazole and has long been used to manage night-time reflux symptoms when added to PPI therapy in patients with GERD.[5,6] Its extensive evidence base and widespread physician familiarity have historically positioned it as a dependable choice in both primary and specialist practice.[1]

Following its precautionary withdrawal from the U.S. market in 2020, interest in H_2 antagonists persisted, particularly among patients who do not require, cannot tolerate, or may not benefit from long-term PPI therapy.[7] In this context, the U.S. Food and Drug Administration (FDA) issued a noteworthy update on 24 November 2025, approving the re-introduction of a reformulated ranitidine product after evaluating new data generated under modern regulatory standards.[8] The approval follows extensive safety testing and manufacturing improvements that address earlier concerns related to the product's stability over its shelf life.[8]

The renewed approval repositions ranitidine as a valuable therapeutic option within the acid-suppression continuum. For patients requiring short-term, rapid symptom relief, those sensitive to PPIs, or those managing polypharmacy in whom interaction risk must be minimized, ranitidine represents a balanced and rational choice. Its rapid onset of action, suitability in elderly populations, and dependable symptom control allow it to serve as a practical intermediary between antacids and PPIs, complementing rather than competing with existing modalities.

The FDA's updated decision provides reassurance for clinicians and patients who previously benefited from ranitidine, noting that strengthened manufacturing oversight and updated quality safeguards support its safe re-introduction.[8] As regulatory agencies worldwide often reference or align with FDA evaluations, this development may encourage broader reassessment of ranitidine under current quality frameworks.

In summary, the FDA's November 2025 approval reflects renewed regulatory confidence in ranitidine and reaffirms its therapeutic relevance in contemporary practice. When used judiciously, ranitidine stands once again as an evidence-supported, practical, and clinically meaningful option for the management of acid-related disorders.

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