



SFDA SAFETY SIGNAL

“A signal is defined by the SFDA as reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information. A signal is a hypothesis together with data and arguments and it is important to note that a signal is not only uncertain but also preliminary in nature”

19-10-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of Prucalopride and the Risk of Suicidal ideation

*The Saudi Food and Drug Authority (SFDA) recommends that all healthcare professionals be aware of the safety signal of **Suicidal ideation** associated with the use of **Prucalopride**. The signal originated as a result of routine pharmacovigilance monitoring activities.*

Introduction

Prucalopride is indicated for symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief.^[1] Suicidal ideation is a contemplation of self-harm or ending one's life and is a critical mental health concern with potentially fatal consequences if not promptly recognized and managed.^[2] This review aims to evaluate this potential risk and to suggest regulatory recommendations if required.

Methodology

The Signal Detection Team at SFDA performed a signal review using the National Pharmacovigilance Center (NPC) database and the World Health Organization (WHO) database, VigiBase, along with a literature review to retrieve all relevant information and assess the potential link between suicidal ideation and prucalopride use.

Results

Cases Review: The Signal Detection Team at SFDA searched the Saudi national database and the WHO database to identify individual case safety reports (ICSRs). The WHO database yielded 47 global case reports, while the NPC database yielded no local cases. The authors used the signal detection tool (VigiLyze) to retrieve global cases.^[3] The authors applied the WHO causality assessment tool to 30 cases with the highest completeness scores. Three cases were considered probably associated with prucalopride, six showed a possible association, two were assessed as unlikely to be associated, and the remaining 19 cases were unassessable.

Datamining: The disproportionality between the observed and expected reporting rates for a drug/adverse drug reaction (ADR) pair is estimated using the Information Component (IC), a tool developed by WHO-UMC to measure the reporting ratio. A positive IC reflects a higher statistical association, while negative values indicate a lower statistical association. The IC result for this drug/ADR combination was 2.8, reflecting a positive statistical association.^[3]



Literature: The Signal Detection Team reviewed regulatory sources and published literature to identify evidence linking prucalopride to the risk of suicidal ideation. The review identified regulatory recognition of this potential risk across two authorities ^[4,5], as well as published case reports describing suicidal ideation occurring shortly after prucalopride administration, supporting an association between prucalopride and suicidal ideation. ^[7,8]

Conclusion

The cumulative weight of evidence identified from global cases, literature, and disproportionality analysis suggests a potential causal association between prucalopride and suicidal ideation. Healthcare professionals and health regulators should be aware of this potential risk in patients receiving prucalopride.

Report Adverse Drug Events (ADRs) to the SFDA

The SFDA urges both healthcare professionals and patients to continue reporting adverse drug reactions (ADRs) resulted from using any medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance Center (NPC)
Saudi Food and Drug Authority-Drug sector
4904 northern ring branch rd
Hittin District
Riyadh 13513 – 7148
Kingdom of Saudi Arabia
Toll free number: 19999
Email: NPC.Drug@sFDA.gov.sa

References

- 1- Resolor 1 mg film-coated tablets | SPC | medicines.ie (2022). <https://www.medicines.ie/medicines/resolor-1-mg-film-coated-tablets-33577/spc>
- 2- Rizvi, A., Harmer, B. and Saadabadi, A. (2024) Suicidal ideation. <https://www.ncbi.nlm.nih.gov/books/NBK565877/>
- 3- VigiLyze (no date). <https://vigilyze.who-umc.org/>
- 4- Food and Drug Administration (2025) MOTEGRITY- Prucalopride tablet, film coated. <https://nctr-crs.fda.gov/fdalabel/services/spl/set-ids/bca1e4c6-4b2b-4876-8ab3-654629c4ff1b/spl-doc?hl#section-6>
- 5- Health Canada (2026) PRODUCT MONOGRAPH INCLUDING PATIENT MEDICATION INFORMATION. https://pdf.hres.ca/dpd_pm/00083160.PDF
- 6- National Institute of Diabetes and Digestive and Kidney Diseases (2019) Prucalopride. <https://www.ncbi.nlm.nih.gov/books/NBK548650/>
- 7- Hawkes, C., Chandran, J.J. and Kozłowska, K. (2025) 'Psychiatric adverse effects from prucalopride in a medically complex adolescent,' Case Reports in Pediatrics, 2025(1), p. 6639748. <https://doi.org/10.1155/crpe/6639748>
- 8- Carnovale, C. et al. (2013) 'Neurological and psychiatric adverse events with prucalopride: case report and possible mechanisms,' Journal of Clinical Pharmacy and Therapeutics, 38(6), pp. 524–525. <https://doi.org/10.1111/jcpt.12087>.