



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”

17-06-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of Aripiprazole and the Risk of Memory impairment

*The Saudi Food and Drug Authority (SFDA) recommends all health care professionals to be aware of the safety signal of **Memory impairment** associated with the use of **Aripiprazole**. The signal has been originated as a result of routine pharmacovigilance monitoring activities.*

Introduction

Aripiprazole is a medication used to manage and treat schizophrenia, mania associated with bipolar I disorder, irritability associated with an autism spectrum disorder, disjunctive therapy in major depressive disorder, and Tourette syndrome. It is a quinolinone antipsychotic that is a partial agonist at the D2 and 5HT-1a receptors and an antagonist at the 5HT-2a receptor. ^[1] Memory impairment: An impairment of memory as manifested by a reduced ability to remember things such as dates and names, and increased forgetfulness. ^[2] The aim of this review is to evaluate the risk of Memory impairment associated with the use of Aripiprazole and to suggest regulatory recommendations if required.

Methodology

Signal Detection team at SFDA performed a signal review using National Pharmacovigilance Center (NPC) database, and World Health Organization (WHO) database, Vigibase, with literature screening to retrieve all related information to assess the potential link between Memory impairment and Aripiprazole use.

Results

Case Review: Signal detection team at SFDA have searched Saudi national database and WHO database to find individual case safety reports (ICSRs). The WHO database resulted in 668 global case reports while no local cases found. The authors used signal detection tool (Vigilyze) to retrieve global cases ^[3]. The author applied WHO Causality assessment tool on the 24 extracted cases with completeness score (0.9 and above). ^[3] Among them, four cases were probably linked to Aripiprazole, nine cases resulted in possible association, and 3 cases resulted in unlikely association, while the remaining eight cases lacked sufficient information for a proper assessment.

Datamining: The disproportionality of the observed and the expected reporting rate for drug/adverse drug reaction pair is estimated using information component (IC), a tool developed by WHO-UMC to measure the reporting ratio. Positive IC reflects higher statistical association while negative values indicates less statistical association. The IC result is (1.1) for this drug/ADR combination which reflects positive statistical association. ^[3]



Literature: The signal team conducted a literature search to identify publications linking this adverse drug reaction to Aripiprazole. The search showed that memory impairment is described in some countries reference safety information. ^[4,5]

Conclusion

The weighted cumulative evidence identified from assessed cases and disproportionality analysis are suggestive for causal association between Aripiprazole and Memory impairment. Health care professionals and health regulators must be aware of the potential risk in drug recipients.

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@sfd.gov.sa

References

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- 2- www.ncbi.nlm.nih.gov. (n.d.). Memory impairment (Concept Id: C0233794) - MedGen - NCBI. [online] Available at: <https://www.ncbi.nlm.nih.gov/medgen/68579#Definition>.
- 3- Vigilyze.who-umc.org. 2026. [online] Available at: <https://vigilyze.who-umc.org/>
- 4- U.S. National Library of Medicine. (2025). DailyMed Label: ARIPIPRAZOLE- aripiprazole orally disintegrating tablet. available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=394ea4a4-3991-4f98-b38f-56e9335d66b3>
- 5- Hres.ca. (2024). PRODUCT MONOGRAPH INCLUDING PATIENT MEDICATION INFORMATION for APO-ARIPIPRAZOLE Tablets. Available at: https://pdf.hres.ca/dpd_pm/00075648.PDF