



SAFETY ALERT

DRAP SAFETY ALERT NO. 53

Safety Alert of Risk of pathological gambling with Aripiprazole.

Date: 27th of March, 2025.

Target Audience.

- Provincial Health Departments/Provincial Pharmacovigilance Centres/Healthcare Commissions;
- Manufacturers and importers of Aripiprazole; and
- Healthcare Professionals.

Background.

The Medicines and Healthcare Products Regulatory Agency (MHRA) in December 2023 reminded healthcare professionals prescribing aripiprazole to be alert to the known risk of patients developing addictive gambling, following a rise in the number of reports received in 2023.

The MHRA informed that from 30 June 2009 to 28 August 2023, it has received 69 Yellow Card reports citing aripiprazole as a suspect medicine for the side effects of gambling or gambling disorder. Across the 69 reports of gambling and gambling disorders, most reports concerned people aged 20 to 40 years, although there were reports of patients up to 60 years of age. In many cases, the patients had no previous history of gambling behaviour. In the majority of cases, cessation of aripiprazole led to a marked reduction or total loss of impulses to gamble.

It was informed that it has been noted since the beginning of 2023 that there has been an increased number of Yellow Card reports for aripiprazole, which include gambling, gambling disorder or obsessive-compulsive disorder in the United Kingdom. A review of the available evidence was considered by the Neurology, Pain and Psychiatry Expert Advisory Group (NPPEAG) of the Commission on Human Medicines (CHM). The NPPEAG noted that the Summary of Product Characteristics (SmPC) and the Patient Information Leaflet (PIL) for aripiprazole contain information regarding pathological gambling and other impulse control disorders. The SmPC states that impulse control disorders may result in harm to the patient and others, if not recognised and advises consideration of dose reduction or stopping the medication if a patient develops increased urges while taking aripiprazole. In reviewing this issue, the NPPEAG recommended that the MHRA remind healthcare professionals and patients of these risks.





Action in Pakistan.

The case was discussed in the 5th meeting of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC) of the DRAP held on 2nd of January, 2025 which decided as per Rule 10(1)(b) and Rule 10(1)(h)(vi) of the Pharmacovigilance Rules, 2022 and recommended the National Pharmacovigilance Centre, DRAP to issue a safety alert to inform healthcare professionals and patient to be alert to the known risk of developing addictive gambling with Aripiprazole.

Therapeutic Good.

Name: Aripiprazole belongs to a class of medicines called antipsychotics. Aripiprazole has 3 approved indications: treatment of schizophrenia in adults and adolescents aged over 15 years; short-term treatment of moderate to severe manic episodes in Bipolar I disorder in adults and adolescents aged 13 years and older; and prevention of a new manic episode in adults who experienced predominantly manic episodes and whose manic episodes responded to aripiprazole treatment.

Advice for Healthcare Professionals.

There has been an increase in the number of reports of gambling disorder and pathological gambling associated with aripiprazole use in the United Kingdom; concerns have also been raised about a lack of awareness of this issue. The UK reports occurred in patients with and without a prior history of gambling disorder, and the majority were reported to resolve upon reduction of dose or stopping treatment with aripiprazole. Healthcare professionals should advise patients and their caregivers to be alert to the development of new or increased urges to gamble and other impulse control symptoms, such as excessive eating or spending, or an abnormally high sex drive. If these symptoms occur in patients, dose reduction or stopping the medication may be considered.

Advice for patients.

Patients are advised not to stop taking aripiprazole without first discussing this with their doctors. Before taking aripiprazole, inform your doctor if you have any personal history of excessive gambling behaviour or impulse control disorders. Tell your doctor if you or your family or friends notice that you are developing urges or cravings to behave in ways that are unusual for you, including behaviours such as addictive gambling, excessive eating or spending, or an abnormally high sex drive.





Guidelines for reporting Adverse Drug Reactions (ADRs).

Both healthcare professionals and patients are requested to report any adverse drug reaction with Aripiprazole to the National Pharmacovigilance Centre (NPC), Drug Regulatory Authority of Pakistan (DRAP) through the [Med Vigilance E-Reporting System](#) (E-forms) available on the DRAP website. Similarly, ADRs can also be reported through the VigiMobile App, which can be downloaded by scanning the barcode available on the DRAP website.

References.

- [Minutes of the 5th meeting of the Pharmacovigilance Risk Assessment Expert Committee.](#)
- [MHRA alert on Aripiprazole and risk of pathological gambling.](#)

