The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

Ajanta Pharma USA, Inc. would like to inform you of a product recall involving Aripiprazole USP, 30 mg. The recalled lot was distributed between 09/19/25 to 03/06/26 to wholesalers and distributors and drug chain stores nationwide.

This recall should be carried out to the retail level.

This recall has been initiated as a precautionary measure due to mislabeling of a bottle labeled "Aripiprazole Tablets, USP 30 mg", which contained Voriconazole tablets instead of Aripiprazole tablets. Both drugs have different therapeutic effects and drug indications. Therefore, considering patient safety, decided to recall the batch.

Suppose a patient is exposed to Voriconazole Tablets USP 50 mg in place of the prescribed Aripiprazole 30 mg. Potential risks may include interruption of Aripiprazole therapy, resulting in recurrence or worsening of psychiatric symptoms. In addition, unintended repeated exposure to Voriconazole may increase the likelihood of adverse effects, including visual disturbances, reversible elevations in hepatic enzymes, skin-related reactions, and clinically significant drug interactions, depending on concomitant medications, underlying medical conditions, and exposure duration. Based on the strength, dosage form, and known safety profile of Voriconazole, such effects would generally be expected to be clinically monitorable and reversible upon discontinuation and appropriate medical management.

Considering the relatively low tablet strength involved (50 mg), the anticipated limited duration of exposure, and the established clinical safety profile of Voriconazole, serious, irreversible, or life-threatening toxicity would not generally be expected under the anticipated exposure conditions. Based on the available evidence and anticipated exposure condition; the health hazard associated with this event is considered to involve a potential for temporary or medically reversible adverse health consequences. The identified risks would generally be expected to be medically manageable with recognition of the error, discontinuation of Voriconazole, reinstatement of appropriate psychiatric therapy, and appropriate clinical monitoring or follow-up as necessary.

PRODUCT: Aripiprazole USP, 30 mg., 30 count

NDC NUMBER: 27241-056-03

BATCH NUMBER: PA00805

EXPIRATION DATE: 01/2029

MANUFACTURER DATE: 02/2025