FDA Benzodiazepine Boxed Warning Update

On September 24th, 2020 the FDA announced that they would be requiring an update to the boxed warnings of benzodiazepine drugs. The reason for the update is to inform patients about the abuse, dependence, and addiction risks that are associated with these products. The FDA now requires manufacturers of these products to describe the risk of misuse, addiction, abuse, dependence, and withdrawal.[1]

Benzodiazepines are commonly prescribed medications. Four of them (alprazolam, clonazepam, diazepam, and lorazepam) are among the top 300 most commonly prescribed drugs in 2020.[2] The combination of the high prescription/dispense rates and the high propensity to cause dependence, makes patient counseling and proper labeling important and urgent. Although benzodiazepine dependence can occur at any dosage, it is most commonly seen in patients taking high doses for long periods of time. Once dependence has formed, the patient is then at risk of going through withdrawal if therapy is abruptly stopped. The symptoms of benzodiazepine withdrawal include, anxiety, insomnia, increased blood pressure, and increased heart rate. Seizures and delirium are severe symptoms associated with benzodiazepine withdrawal. Due to the potential of abuse, dependence, and withdrawal prescribers should take caution before prescribing benzodiazepines. Before prescribing benzodiazepines, prescribers should assess their patients' risk of abuse and addiction. Prescribers should also limit the doses and durations of benzodiazepines to the lowest effective dose and for the shortest duration possible. To discontinue therapy with benzodiazepines, patient's doses should be tapered off gradually to prevent triggering withdrawal.[3,4]

References

1. FDA. FDA Requiring Boxed Warning Updated to Improve Safe Use of Benzodiazepine Drug Class. Food and Drug Association. Available at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-requiring-boxed-warning-updated-improve-safe-use-benzodiazepine-drug-class. Accessed 10/01/2020
2. Kolesar J, Vermeulen L. Top 300 Pharmacy Drug Cards 2020-2021. McGraw Hill.
3. Longo L, Johnson B. Addiction: Part 1. Benzodiazepines Side Effects, Abuse Risk and Alternatives. American Association of Family Physicians. Available at: https://www.aafp.org/afp/2000/0401/p2121.html. Accessed 10/01/2020
4. DEA. Benzodiazepines Fact Sheet. Drug Enforcment Agency. Available at: https://www.dea.gov/sites/default/files/2020-06/Benzodiazepenes-2020_1.pdf. Accessed 10/01/2020

Prepared by: Jordan Eckman, Doctor of Pharmacy Candidate