Caplyta (lumateperone) and Parkinsonism

In response to your inquiry regarding parkinsonism associated with Caplyta (lumateperone) and use of Cogentin (benztropine) the following information is available.

Caplyta (lumateperone) is indicated for the treatment of schizophrenia in adults.[1]

Summary

Parkinsonism is one clinical diagnosis correlated with extrapyramidal symptoms (EPS) that are associated with antipsychotic use. Parkinsonism, also referred as drug-induced parkinsonism (DIP), can be linked with antipsychotic use, and may present as tremor, rigidity, and slowing of motor function.[2] Cogentin (benztropine) is approved for all forms of Parkinson's and may be useful in the treatment of DIP.[3]

- Often, treatment for DIP involves removal of offending agent.[4]
- Patients who cannot stop their antipsychotic due to disease state, may switch to an antipsychotic with a lower risk of EPS.[4]
- DIP usually resolves weeks to months after removal of offending agent but may persist in 10-50% of patients.[4]
- Cogentin (benztropine) is available in oral, intramuscular, and intravenous routes.[3]
- Caplyta (lumateperone) does not contain a warning or precaution for EPS.[1]

While not a warning or precaution for Caplyta (lumateperone), clinicians should consider the risk and monitor their patients for signs or symptoms of DIP or EPS before initiating Cogentin (benztropine).

Supporting Data

- In a randomized, double-blinded, phase-3 study of Caplyta (lumateperone) versus placebo, 449 patients were evaluated for safety with 150 receiving lumateperone 42 mg, 150 receiving lumateperone 28 mg, and 149 receiving placebo.[5]
    - In total, 14 patients had 1 or more EPS treatment-emergent adverse events (TEAEs), 6 (4.0%) from the 42 mg group, 4 (2.7%) from the 28 mg group, and 4 (2.7) from the placebo group. There were 12 reports of akathisia, 2 of dyskinesia, and 1 of dystonia.
    - Treatment with lumateperone was not associated with and increased EPS as measured by the Simpson-Angus Scale (SAS), Barnes Akathisia Rating Scale (BARS), or Abnormal Involuntary Movement Scale (AIMS).
    - 3 patients (2.0%) from the 42 mg group, 1 patient (0.7%) from the 28 mg group, and 4 patients (2.7%) in the placebo group used benztropine as a rescue medication for EPS during the 28-day treatment period.
- In an open-label, outpatient, crossover study of Caplyta (lumateperone) 42 mg, 301 patients were included in the safety evaluation.[6]
    - EPS related TEAEs were only reported in 1% of the population.

    - There was no change in EPS as shown by BARS Total, BARS Global, AIMS, and SAS score.
    - 21 patients (7.0%) used benztropine as a rescue medication for EPS during the 6-week treatment period.
- There is no known drug interaction between Caplyta (lumateperone) and Cogentin (benztropine).[7]

Overall, the instance of DIP and EPS is low with the use of Caplyta (lumateperone), however, clinicians should carefully weigh the risks versus benefits prior to initiating Caplyta (lumateperone) and continually monitor patients for signs or symptoms of new or worsening DIP and EPS. While there is no known drug indication between Caplyta (lumateperone) and Cogentin (benztropine), clinicians should weigh the risks versus benefits of Cogentin (benztropine) prior to its initiation.

References

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