ADASUVE is contraindicated in patients with the following:

- Current diagnosis or history of asthma, chronic obstructive pulmonary disease (COPD), or other lung disease associated with bronchospasm
- Acute respiratory signs/symptoms (e.g., wheezing)
- Current use of medications to treat airways disease, such as asthma or COPD
- History of bronchospasm following ADASUVE treatment
- Known hypersensitivity to loxapine or amoxapine. Serious skin reactions have occurred with oral loxapine and amoxapine

ADASUVE can cause bronchospasm that has the potential to lead to respiratory distress and respiratory arrest. Administer ADASUVE only in an enrolled healthcare facility that has immediate access on site to supplies and personnel trained to manage acute bronchospasm, and ready access to emergency response services. Facilities must have a short-acting bronchodilator (e.g., albuterol), including a nebulizer and inhalation solution, for the immediate treatment of bronchospasm. Prior to administering ADASUVE, screen patients regarding a current diagnosis, history, or symptoms of asthma, COPD and other lung diseases, and examine (including chest auscultation) patients for respiratory signs. Monitor for signs and symptoms of bronchospasm following treatment with ADASUVE.

Because of the risk of bronchospasm, ADASUVE is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ADASUVE REMS. Increased Mortality in Elderly Patients With Dementia-Related Psychosis Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ADASUVE is not approved for the treatment of patients with dementia-related psychosis.

ADASUVE may increase the risk of falls, which could cause fractures or other injuries. Patients taking antipsychotics with certain health conditions or those on long-term therapy should be evaluated by their healthcare professional for the potential risk of falls

Use ADASUVE with caution in patients with a history of seizures or with conditions that lower the seizure threshold. Seizures have occurred in patients treated with oral loxapine, and can also occur in epileptic patients

Use caution when driving or operating machinery. ADASUVE can impair judgment, thinking, and motor skills

The potential for cognitive and motor impairment is increased when ADASUVE is administered concurrently with other CNS depressants

Treatment with antipsychotic drugs caused an increased incidence of stroke and transient ischemic attack in elderly patients with dementia-related psychosis; ADASUVE is not approved for the treatment of patients with dementia-related psychosis

Use of ADASUVE may exacerbate glaucoma or cause urinary retention

The most common adverse reactions (incidence ≥2% and greater than placebo) in clinical studies in patients with agitation treated with ADASUVE were dysgeusia, sedation, and throat irritation

Pregnancy Category C.

Neonates exposed to antipsychotic drugs during the third trimester of pregnancy are at risk of extrapyramidal and/or withdrawal symptoms after delivery. ADASUVE should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus

Nursing mothers: Discontinue drug or nursing, taking into account the importance of the drug to the mother

The safety and effectiveness of ADASUVE in pediatric patients have not been established