

# PRODUCT INFORMATION



## adasuve<sup>®</sup> (loxapine) inhalation powder

### INDICATIONS AND USAGE

ADASUVE<sup>®</sup> (loxapine) inhalation powder, for oral inhalation use, is a typical antipsychotic indicated for the acute treatment of agitation associated with schizophrenia or bipolar I disorder in adults. Efficacy was demonstrated in 2 trials in acute agitation: one in schizophrenia and one in bipolar I disorder.<sup>1</sup>

Limitations of Use: As part of the ADASUVE Risk Evaluation and Mitigation Strategy (REMS) Program to mitigate the risk of bronchospasm, ADASUVE must be administered only in an enrolled healthcare facility.<sup>1</sup>

### HOW SUPPLIED

	SINGLE UNIT	SALEABLE UNIT
NDC#	57844-510-11	57844-510-55
PACKAGING	One single-use, disposable inhaler containing 10 mg of loxapine in a sealed foil pouch.	One carton containing 5 single-use, disposable 10 mg loxapine inhalers, each inhaler individually sealed in a foil pouch.

### DOSAGE AND ADMINISTRATION

ADASUVE must be administered only by a healthcare professional. ADASUVE is administered by oral inhalation only. The recommended dose for acute agitation is 10 mg administered by oral inhalation, using a single-use inhaler. Administer only a single dose within a 24-hour period.<sup>1</sup>

Prior to administering ADASUVE, screen all patients for a history of asthma, COPD, or other pulmonary disease, and examine patients (including chest auscultation) for respiratory signs (eg wheezing).<sup>1</sup>

### ⚠️ IMPORTANT SAFETY INFORMATION

#### WARNING: BRONCHOSPASM and INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

##### Bronchospasm

**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.**

### BILLING CODES

The following codes may be used to communicate services rendered when filing claims for ADASUVE and are provided for informational purposes only. Note that specific guidance or direction on the submission of claims offered by the payer supercedes the codes listed below, and providers are responsible for the accuracy of any claims, invoices, or related documentation submitted to payers.

<b>NDC*</b> 57844-0510-11	One single-use, disposable inhaler containing 10 mg of loxapine in a sealed foil pouch
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<b>CPT code</b>	[code # and description]
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<b>C code</b>	C9497 (loxapine, inhalation powder)
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<b>J code</b>	[code # and description]
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\*Note that the product's NDC# has been "zero-filled" to ensure creation of an 11-digit code that meets CMS standards. The zero-fill location is indicated in bold.

### HOW TO ORDER

<b>DISTRIBUTORS</b>	<b>McKesson Plasma and Biologics</b>	<b>Smith Medical Partners</b>
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<b>CONTACT INFORMATION</b>	mckesson.com 877-625-2566	smpspecialty.com 800-292-9653
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### ADASUVE REMS

ADASUVE is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ADASUVE REMS. For information on the ADASUVE Risk Evaluation and Mitigation Strategy (REMS) program, visit [adasuverems.com](http://adasuverems.com) or call **855-755-0492**.

### MORE INFORMATION

Visit [adasuve.com](http://adasuve.com) or call **888-832-6378**.

PLEASE SEE ACCOMPANYING FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNINGS.



**adasuve**<sup>®</sup>  
(loxapine) inhalation powder

**⚠ IMPORTANT SAFETY INFORMATION (continued)**

- 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 (eg, 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 must be administered only by a healthcare professional
- Prior to administration, all patients must be screened for a history of pulmonary disease and examined (including chest auscultation) for respiratory abnormalities (eg, wheezing)
- Administer only a single 10 mg dose of ADASUVE within a 24-hour period by oral inhalation using the single-use inhaler
- After ADASUVE administration, patients must be monitored for signs and symptoms of bronchospasm at least every 15 minutes for at least 1 hour
- ADASUVE can cause sedation, which can mask the symptoms of bronchospasm
- Antipsychotic drugs can cause a potentially fatal symptom complex called Neuroleptic Malignant Syndrome (NMS), manifested by hyperpyrexia, muscle rigidity, altered mental state, irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia. Associated features can include escalated serum creatine phosphokinase (CPK) concentration, rhabdomyolysis, elevated serum and urine myoglobin concentration, and renal failure. If NMS occurs, immediately discontinue antipsychotic drugs and other drugs that may contribute to the underlying disorder, monitor and treat symptoms, and treat any concomitant serious medical problems
- ADASUVE can cause hypotension, orthostatic hypotension, and syncope. Use with caution in patients with known cardiovascular disease, cerebrovascular disease, or conditions that would predispose patients to hypotension. In the presence of severe hypotension requiring vasopressor therapy, epinephrine should not be used
- Use ADASUVE with caution in patients with a history of seizures or with conditions that lower the seizure threshold. ADASUVE lowers 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  $\geq 2\%$  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

**PLEASE SEE ACCOMPANYING FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNINGS.**

**Reference:** 1. Adasuve [package insert]. Mountain View, CA: Alexza Pharmaceuticals, Inc; September 2016.