

Nursing Mothers

Counsel patients and caregivers regarding the potential risk to the infant [see *Use in Specific Populations* (8.3)].

Medication Guide

MEDICATION GUIDE ADASUVE™ (AD-uh-soov) (loxapine) Inhalation Powder

Read this Medication Guide before you start taking ADASUVE and each time it is given to you. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or your treatment. You should share this information with your family members and caregivers.

What is the most important information I should know about ADASUVE?

ADASUVE is available only through the ADASUVE Risk Evaluation and Mitigation Strategy (REMS) Program. The healthcare facility must be enrolled in the ADASUVE REMS Program before you can be given ADASUVE.

ADASUVE may cause serious side effects, including:

- **Narrowing of the airways (bronchospasm) that can cause you to have problems breathing or to stop breathing.** People who have asthma or other airway or lung problems, such as chronic obstructive pulmonary disease (COPD), have a higher risk of bronchospasm when taking ADASUVE. Symptoms of bronchospasm may include:
 - wheezing
 - coughing
 - chest tightness
 - shortness of breath

Tell your healthcare provider right away if you have any of these symptoms of bronchospasm after taking ADASUVE.

Your healthcare provider should check you for breathing problems before and after you take ADASUVE.

- **Increased risk of death in elderly patients with dementia-related psychosis.** Medicines like ADASUVE can raise the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). ADASUVE is not approved for the treatment of patients with dementia-related psychosis.

What is ADASUVE?

ADASUVE is a prescription medicine that is inhaled through your mouth and is used to treat acute agitation in adults with schizophrenia or bipolar I disorder. It is not known if ADASUVE is safe and effective in children.

Who should not take ADASUVE?

Do not take ADASUVE if you:

- have or have had asthma, chronic obstructive pulmonary disease (COPD), or other airway or lung problems that can cause bronchospasm
- are having problems with wheezing, coughing, chest tightness, or shortness of breath
- are taking medicines to treat asthma or COPD
- have taken ADASUVE before and had bronchospasm
- are allergic to loxapine or amoxapine

What should I tell my healthcare provider before taking ADASUVE?

Before you take ADASUVE, tell your healthcare provider if you:

- have high or low blood pressure
- have or have had heart problems or stroke
- have or have had seizures (convulsions)
- drink alcohol or use street drugs
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if ADASUVE will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ADASUVE passes into your breast milk. You and your healthcare provider should decide if you will take ADASUVE if you are breastfeeding.

Tell your doctor about all medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

- ADASUVE and other medicines may affect each other causing side effects. ADASUVE may affect the way other medicines work, and other medicines may affect the way ADASUVE works.

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure.

Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

How should I take ADASUVE?

- Your healthcare provider will show you how to take ADASUVE right before you take it.
- Take ADASUVE exactly as your healthcare provider shows you to take it.
- ADASUVE is for oral inhalation only.

What should I avoid while taking ADASUVE?

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how ADASUVE affects you.
- Do not drink alcohol while taking ADASUVE. It can increase your chances of getting serious side effects.

What are the possible side effects of ADASUVE?

ADASUVE can serious side effects, including:

- See "What is the most important information I should know about ADASUVE?"
- **neuroleptic malignant syndrome (NMS)**. NMS is a rare but serious condition that may cause death. Symptoms of NMS may include:
 - high fever
 - stiff muscles
 - confusion
 - sweating
 - changes in pulse, heart rate, and blood pressure

Tell your healthcare provider right away if you have any of these symptoms of NMS after taking ADASUVE.

- **low blood pressure (hypotension), lightheadedness, or fainting**
- **seizures (convulsions)**
- **severe sleepiness and difficulty with potentially dangerous activities such as driving**
- **worsening of glaucoma**
- **difficulty urinating**

The most common side effects of ADASUVE include:

- bad, bitter, or metallic taste in your mouth (dysgeusia)
- sleepiness (especially when used with other drugs that cause sleepiness)
- sore throat

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of ADASUVE. For more information ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of ADASUVE.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

This Medication Guide summarizes the most important information about ADASUVE. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about ADASUVE that is written for health professionals.

For more information, go to www.ADASUVE.com or call 1-800-284-0062.

What are the ingredients in ADASUVE?

Active Ingredient: lorazepam

Inactive Ingredients: none

This Medication Guide has been approved by the U.S. Food and Drug Administration

Manufactured by: Alexza Pharmaceuticals, Inc., Mountain View, CA 94043

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