ADASUVE® (loxapine) Inhalation Powder

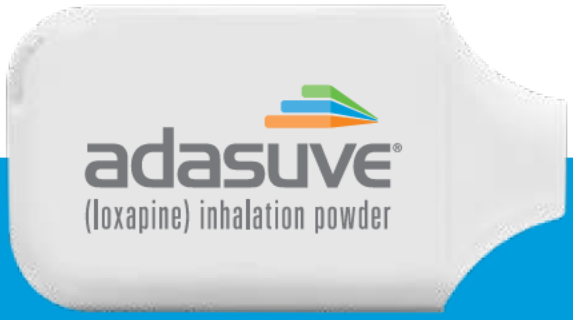
ADASUVE

Risk Evaluation and Mitigation Strategy (REMS) Program

Healthcare Provider Brochure

This brochure includes information about:

- The risk of bronchospasm
- Recommendations for safe use of ADASUVE
- What to communicate to your patients
- Instructions for Healthcare Facility enrollment



Please share this Healthcare Provider Brochure with anyone in your healthcare setting involved in prescribing, dispensing, or administering ADASUVE or who monitors patients after treatment with ADASUVE.

Questions about ADASUVE?

Contact ADASUVE Medical Information at **800-284-0062** or email **customer.services@galen-pharma.com.**

Please see Prescribing Information, including Boxed Warning.

About This Brochure

The Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of ADASUVE® outweigh the risk of bronchospasm that has the potential to lead to respiratory distress and respiratory arrest. Patients with asthma, chronic obstructive pulmonary disease (COPD), or other pulmonary diseases are at increased risk of bronchospasm after taking ADASUVE. This brochure contains information for providers on the risks and safe use of ADASUVE, as well as information on healthcare facility enrollment requirements of the ADASUVE REMS Program; ADASUVE can only be distributed to and administered in healthcare facilities that are enrolled in the ADASUVE REMS Program.

Indications and Usage

ADASUVE is a typical antipsychotic indicated for the acute treatment of agitation associated with schizophrenia or bipolar I disorder in adults.

"Psychomotor agitation" is defined in DSM-IV as "excessive motor activity associated with a feeling of inner tension." Patients experiencing agitation often manifest behaviors that interfere with their care (eg, threatening behaviors, escalating or urgently distressing behavior, self-exhausting behavior), leading clinicians to the use of rapidly absorbed antipsychotic medications to achieve immediate control of the agitation.

The efficacy of ADASUVE was established in one study of acute agitation in patients with schizophrenia and one study of acute agitation in patients with bipolar I disorder.

Limitations of Use:

As part of the ADASUVE REMS Program to mitigate the risk of bronchospasm, ADASUVE must be administered only in an enrolled healthcare facility.

Important Safety Information

Contraindications

ADASUVE® is contraindicated in patients with the following:

- Current diagnosis or history of asthma, COPD, or other lung disease associated with bronchospasm
- Acute respiratory symptoms or signs (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 (eg, serious skin reaction)

Boxed Warning for ADASUVE®

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 (eg, 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.

Restricted Use to Mitigate Bronchospasm

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. Under the ADASUVE REMS Program, healthcare facilities and distributors must enroll in the program.

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.

These risks do not constitute a complete list of all the risks associated with ADASUVE. Please see the enclosed Prescribing Information for more information regarding the risks associated with ADASUVE.

Steps for the Safe Use of ADASUVE®

This poster is available to enrolled healthcare facilities to reinforce how to use ADASUVE safely. Healthcare facilities are encouraged to post this where ADASUVE will be administered. Additional copies can be ordered at www.adasuverems.com or by calling **855-755-0492.**

ADASUVE is indicated for the acute treatment of agitation associated with schizophrenia or bipolar I disorder in adults.

ADASUVE can cause bronchospasm that has the potential to lead to respiratory distress and respiratory arrest. Patients with asthma, chronic obstructive pulmonary disease (COPD), or other lung disease associated with bronchospasm are at increased risk of bronchospasm.

Steps for Safe Use of ADASUVE	
SCREEN	☐ Ask if patient is taking medication to treat asthma or COPD and/or check medical records
	☐ Ask if patient has a current diagnosis or history of asthma, COPD, or other lung disease, and/or check medical records
	☐ Examine patients (including chest auscultation) for respiratory abnormalities (e.g., wheezing)
	☐ **Do not use in patients with acute respiratory signs or symptoms; with a current diagnosis or history of asthma, COPD, or other lung disease associated with bronchospasm; or with current use of medications to treat airways disease, such as asthma or COPD**
COUNSEL	☐ Counsel patient/caregiver on potential for bronchospasm that may occur after dosing and the need for them to report symptoms immediately
MONITOR	☐ Monitor patient every 15 minutes for at least 1 hour after treatment for signs and symptoms of bronchospasm including chest auscultation
	☐ Ask patient every 15 minutes about any difficulty breathing
If bronchospasm occurs MANAGE	☐ Treat bronchospasm with an inhaled short-acting beta-agonist bronchodilator (e.g., albuterol)
	☐ If medically necessary, provide additional therapy for bronchospasm per asthma guidelines

Reporting Adverse Events

Healthcare professionals should understand the importance of reporting events of bronchospasm that require emergency response services, in addition to any fatalities that occur following ADASUVE treatment. To report suspected adverse events, contact ADASUVE Medical Information at **800-284-0062** or email **customer.services@galen-pharma.com**. Adverse events may also be reported to FDA at **1-800-FDA-1088** or **www.fda.gov/medwatch/report.htm.**

Patient Counseling

Discuss the risks associated with ADASUVE® therapy with patients and their caregivers, including the safe use of ADASUVE.

Helping Patients and Caregivers Understand the Risks

- Explain that in certain patients, ADASUVE may cause narrowing of the airways (bronchospasm) and may cause them to wheeze, cough, feel chest tightness, or have shortness of breath
- Ask patients to tell you if they are currently taking any medications to treat asthma, COPD, or a breathing problem or have a history of asthma, COPD, or other respiratory conditions
- Inform patients that other serious side effects may occur, such as neuroleptic malignant syndrome, tardive dyskinesia, orthostatic hypotension, or seizures
- Inform patients about other common side effects that may include dysgeusia (taste) and sleepiness

Helping Patients and Caregivers Report the Signs and Symptoms of Bronchospasm

- Ask patients to tell you immediately if they experience difficulty breathing or feel chest tightness or wheezing after they have received a treatment
- Tell patients you have a medicine available to treat any breathing problems that might occur

ADASUVE is provided with a Medication Guide. If practical, please review the Medication Guide with your patient or their caregiver before administering the product.

About ADASUVE®

Administration of ADASUVE

- ADASUVE is only administered by oral inhalation
- ADASUVE must be administered only by a healthcare professional, in an enrolled healthcare facility
- Administer only a single dose per patient within a 24-hour period

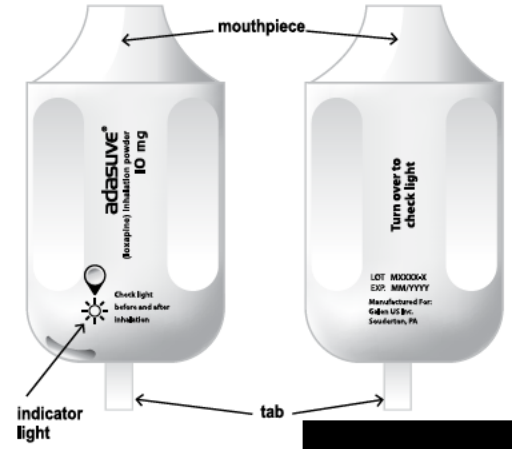
Required Examination Prior to Dosing

Prior to administering ADASUVE, screen all patients for current use of medications to treat asthma or COPD, a history of asthma, COPD, or other lung disease, and examine patients (including chest auscultation) for respiratory abnormalities (eg, wheezing).

Becoming Familiar With ADASUVE

- ADASUVE is provided in a sealed pouch
- The indicator light is off when ADASUVE is removed from the pouch
- The indicator light turns on (green) when the tab is pulled out. The inhaler is then ready for use
- The indicator light turns off after the patient inhales. This indicates that the dose has been delivered
- If the indicator light does NOT turn off, the dose has NOT been delivered. See Instructions for Use

The pictures below show the important features of the ADASUVE product (both sides shown).



Important Administration Instructions

1. Open the pouch.

When ready to use, tear open the foil pouch and remove the inhaler from the package.

When the ADASUVE® inhaler is removed from the pouch, the indicator light is off.

2. Pull tab.

Firmly pull the plastic tab from the rear of the inhaler. Check that the green light turns on. This indicates that the inhaler is ready for use. Use the inhaler within 15 minutes after removing the tab to prevent automatic deactivation of the inhaler. The green light will turn off, indicating that the inhaler is not usable. Discard the inhaler after one use.

3. Explain procedures to the patient.

Explain the administration procedures to the patient prior to use, and advise the patient that it is important to follow the instructions. Inform the patient that the inhaler may produce a flash of light and a clicking sound, and it may become warm during use. These are normal.

4. Instruct the patient to exhale.

Instruct the patient to hold the inhaler away from the mouth and breathe out fully to empty the lungs.

5. Instruct the patient to inhale.

Instruct the patient to put the mouthpiece of the inhaler between the lips, close the lips, and inhale through the mouthpiece with a steady deep breath. Check that the green light turns off indicating that the dose has been delivered.

6. Instruct the patient to hold breath.

Instruct the patient to remove the mouthpiece from the mouth and hold the breath for as long as possible, up to 10 seconds.

IMPORTANT

If the green light remains on after the patient inhales, the dose of ADASUVE has NOT been delivered. Instruct the patient to repeat Step 4, Step 5, and Step 6 up to 2 additional times. If the green light still does not turn off, discard the inhaler and use a new one.

Monitoring to Assess Safety

Monitor the patient for signs and symptoms of bronchospasm after ADASUVE administration. Perform a physical examination, including chest auscultation, at least every 15 minutes for at least 1 hour after ADASUVE administration.

Prescribing and Administering ADASUVE® at Your Healthcare Facility

- **ADASUVE will be dispensed only to patients in certain healthcare facilities that are enrolled in the ADASUVE REMS Program**
- **Wholesalers/distributors will ship ADASUVE only to enrolled healthcare facilities**

Healthcare Facility Qualifications for Enrollment

Each healthcare facility must be able to provide:

- Immediate access on site to supplies and personnel trained to manage acute bronchospasm and ready access to emergency response services. This healthcare facility must have a short-acting bronchodilator (e.g., albuterol), including a nebulizer and inhalation solution, for the immediate treatment of bronchospasm
- Medical/psychiatric (physicians, nurses, etc) staff on site at all times (24 hours a day/7 days a week) trained to manage acute bronchospasm
- Procedures, protocols, and/or order sets to ensure the following:
  - Patients are screened, prior to treatment with ADASUVE, for a history of pulmonary disease and for acute respiratory signs and symptoms by physical exam, including taking vital signs and chest auscultation, and inquiring if patient is taking medication to treat asthma or COPD
  - Patients are monitored at least every 15 minutes for a minimum of one hour following treatment with ADASUVE for signs and symptoms of bronchospasm, including taking vital signs and chest auscultation
  - Administration of ADASUVE is limited to 1 dose per patient within 24 hours
- Healthcare providers within the facility (prescribers, nurses, monitoring staff, or pharmacists) who are trained on safe use of ADASUVE using the ADASUVE REMS Education Program

Prescribing and Administering ADASUVE® at Your Healthcare Facility (cont'd)

Authorized Healthcare Facility Representative

For each healthcare facility, an ***authorized healthcare facility representative*** is required to review the **ADASUVE REMS Education Program**, and complete and sign the **Healthcare Facility Enrollment Form** acknowledging that the enrolled healthcare facility meets specific requirements. This representative may be a pharmacist or another healthcare professional with the appropriate level of responsibility within the healthcare facility, who is authorized to act on behalf of the facility.

To enroll your healthcare facility, please read and complete the Healthcare Facility Enrollment Form that is available at **www.adasuverems.com**.

For questions about the ADASUVE REMS Program, please call **855-755-0492**.

ADASUVE® REMS Materials for Enrolled Healthcare Facilities

The following materials are part of the ADASUVE REMS Program and will assist enrolled healthcare facilities in complying with ADASUVE REMS requirements. They are available to review, order, or print at www.adasuverems.com or by calling 855-755-0492.

1. ADASUVE REMS Education Program
Must be reviewed by all healthcare providers within an enrolled healthcare facility who will be prescribing or administering ADASUVE, or observing patients after ADASUVE is administered.

2. Steps for Safe Use of ADASUVE Poster
Should be posted where ADASUVE is administered within enrolled healthcare facilities.

3. Order Set/Protocol Template
For use by enrolled healthcare facilities to assist with designing procedures, protocols, and/or order sets that meet the requirements of the ADASUVE REMS Program.

4. ADASUVE Healthcare Provider Brochure
Contains information for providers on the risks and safe use of ADASUVE, as well as information on healthcare facility enrollment requirements of the ADASUVE REMS Program.

Other resources are available at www.adasuverems.com

- **Healthcare Facility Enrollment Information and Form**
- **Prescribing Information**
- **ADASUVE Instructions for Use**
- **ADASUVE Medication Guide**

Reporting Adverse Events

Healthcare professionals should report suspected adverse events associated with ADASUVE® treatment to ADASUVE Medical Information at **800-284-0062** or email **customer.services@galen-pharma.com.** In addition, adverse events may be reported to the FDA MedWatch Reporting System by the following methods:

- Online at **www.fda.gov/medwatch/report.htm**
- Phone at **1-800-FDA-1088**
- Fax at **1-800-FDA-0718**, using the MedWatch Form 3500 (available at **www.fda.gov/medwatch/getforms.htm**)

The Prescribing Information and Medication Guide are also available from your local sales representative or by calling **800-284-0062** or email **customer.services@galen-pharma.com.**

Please share this Healthcare Provider Brochure with anyone in your healthcare facility who is involved in prescribing, dispensing, or administering ADASUVE or who monitors patients after treatment with ADASUVE.

Please see Prescribing Information, including Boxed Warning.

GALEN

©2017 Galen US Inc. All rights reserved.
PMR-JUN-2017-0014. August 2017.