ADASUVE®

(LOXAPINE) INHALATION POWDER

EDUCATION PROGRAM for HEALTHCARE SETTINGS

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Alexza Pharmaceuticals

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Mountain View, CA 94043

WHAT IS ADASUVE®?

- ADASUVE is a drug-device combination product that delivers an aerosol of the antipsychotic agent loxapine in a single oral inhalation.
- ADASUVE is indicated for the acute treatment of agitation associated with schizophrenia or bipolar I disorder in adults.
- 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 (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.
- Limitation of Use: As part of the ADASUVE REMS Program to mitigate the risk of bronchospasm, ADASUVE must be administered only in an enrolled healthcare setting.

BOXED WARNING (BRONCHOSPASM)

- ADASUVE can cause bronchospasm that has the potential to lead to respiratory distress and respiratory arrest, particularly in patients with lung diseases.
- **Administer ADASUVE only in a certified healthcare setting that has immediate access on site to supplies and healthcare professionals competent in the management of acute bronchospasm and access to emergency assistance for symptoms that require immediate medical attention.** Certified healthcare settings must have a short-acting bronchodilator (e.g., albuterol) available for the immediate treatment of bronchospasm; this short-acting bronchodilator can be delivered by inhaler (with spacer) or nebulizer.
- Prior to administering ADASUVE, screen patients regarding a current diagnosis, history, or symptoms of asthma, COPD and other lung diseases, and assess (including chest auscultation) patients for respiratory signs.
- Monitor for signs and symptoms of bronchospasm following treatment with ADASUVE.

WHAT IS THE ADASUVE REMS (RISK EVALUATION AND MITIGATION STRATEGY)?

- The ADASUVE REMS is a safety program that helps ensure that the benefits of ADASUVE outweigh its risks
- The ADASUVE REMS is required by the Food and Drug Administration (FDA) because ADASUVE can cause bronchospasm that has the potential to lead to respiratory distress and respiratory arrest, particularly in contraindicated patients with lung diseases

ADASUVE REMS – OVERVIEW

- ADASUVE is dispensed only in certified healthcare settings that have:
    - Immediate access on site to supplies and healthcare professionals competent in the management of acute bronchospasm, and access to emergency assistance for symptoms that require immediate medical attention. Healthcare settings must have a short-acting bronchodilator (e.g., albuterol) available, delivered by inhaler (with spacer) or nebulizer, for the immediate treatment of bronchospasm.
    - Processes and procedures in place to ensure that patients are screened for conditions for which ADASUVE is contraindicated and monitored for signs of bronchospasm.
- Wholesalers/distributors will ship ADASUVE only to certified healthcare settting

HEALTHCARE SETTING REQUIREMENTS: AUTHORIZED REPRESENTATIVE

- The Authorized Representative is a healthcare professional with the appropriate level of responsibility within the healthcare setting and is authorized to act on behalf of the healthcare setting.
- For each certified healthcare setting, an Authorized Representative is required to:
    - Review the ADASUVE Education Program for Healthcare Settings
    - Complete and sign the *Healthcare Setting Enrollment Form*, and submit the completed form on-line, via fax, or via email

  The *Healthcare Setting Enrollment Form* is available at www.adasuverems.com or by calling 855-755-0492

- Any new Authorized Representative must recertify the healthcare setting

ADASUVE REMS STAKEHOLDER REQUIREMENTS

Healthcare Setting	Patients
• Must have immediate access to supplies and healthcare professionals competent in the management of acute bronchospasm, and access to emergency assistance for symptoms that require immediate medical attention. • Must have a short-acting bronchodilator (e.g., albuterol), for the immediate treatment of bronchospasm; this short-acting bronchodilator can be delivered by inhaler (with spacer) or nebulizer. • Establish processes and procedures to (1) assess the patient for respiratory abnormalities before administration (medical history, medication history, and chest auscultation), (2) monitor the patient for a minimum of 1 hour after administration for bronchospasm, (3) provide that no more than a single dose of ADASUVE is administered within a 24-hour period, and (4) provide that ADASUVE is not dispensed outside of the certified healthcare setting. • Do not administer more than one dose of ADASUVE in a 24-hour period. • Do not dispense ADASUVE for use outside of the certified healthcare setting. • Do not distribute, transfer, or loan or sell ADASUVE. • Maintain appropriate documentation that all processes and procedures are in place and are being followed. • Comply with audits.	• Before treatment administration, complete a medical history and/or medication history if requested, and be assessed for signs and symptoms of breathing problems if requested by the prescriber. • During treatment, for a minimum of 1 hour, be monitored for signs and symptoms of bronchospasm.

Healthcare Setting Processes and Procedures Requirements: Patient Screening, Monitoring, and Management

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
	If current diagnosis cannot be determined or if there is no access to patient's medical records, treat with ADASUVE only after assessing 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 for at least 1 hour after treatment for signs and symptoms of bronchospasm
 If bronchospasm occurs MANAGE	Treat bronchospasm with an inhaled short-acting beta-agonist bronchodilator (e.g., albuterol)

RESOURCES AVAILABLE

- The ADASUVE REMS Education Program for Healthcare Settings (this document) is available to review or print at www.adasuverems.com

- Other Resources available at www.adasuverems.com
  - *Healthcare Setting Enrollment Form*
  - Prescribing Information
  - ADASUVE Medication Guide

REPORTING ADVERSE EVENTS ASSOCIATED WITH ADASUVE

Healthcare professionals should report all events of bronchospasm, in addition to any fatalities that occur following ADASUVE treatment.

Suspected adverse events may be reported by the following methods:

- ADASUVE Medical Information at 800-284-0062 or email medinfo@alexza.com
- FDA at 1-800-FDA-1088
- FDA at www.fda.gov/medwatch/report.htm

PROCEDURES AND PROTOCOLS TEMPLATE FOR SAFE USE OF ADASUVE

This template is to be used as a guideline for developing procedures and protocols around the use of ADASUVE to ensure that REMS requirements are being met.

INDICATION

- ☐ Agitation associated with bipolar I disorder
- ☐ Agitation associated with schizophrenia

PATIENT SCREENING

Prior to dosing:
Inquire and/or check medical records for:

- ☐ current diagnosis or history of asthma, COPD or other lung diseases associated with bronchospasm
- ☐ current use of medications to treat airways disease, such as asthma or COPD
- ☐ history of bronchospasm following ADASUVE treatment
- ☐ known hypersensitivity (e.g. serious skin reaction) to loxapine or amoxapine

Assess for acute respiratory signs and symptoms (including chest auscultation):

☐ wheezing ☐ cough ☐ dyspnea ☐ other: _____

If any of the above screening is positive, DO NOT USE ADASUVE. ADASUVE is contraindicated in these patients.

DOSE ADMINISTRATION

Limit ADASUVE use to a single dose per patient within a 24-hour period.

POST-TREATMENT OBSERVATION / MONITORING

Patient must be monitored for at least 1 hour after treatment for signs / symptoms of bronchospasm.

MANAGEMENT OF BRONCHOSPASM

- ☐ Immediately treat patient with short acting bronchodilator (e.g. albuterol) delivered by inhaler (with spacer) or nebulizer
- ☐ Report any case of bronchospasm

Phone 855-755-0492 Fax 855-755-0493 www.adasuverems.com