

## IMPORTANT DRUG WARNING

- Risk of bronchospasm with ADASUVE® (loxapine) inhalation powder
- ADASUVE is available only in enrolled healthcare facilities, under an FDA-required REMS Program

Dear Healthcare Professional:

This letter contains important safety information for ADASUVE (loxapine) inhalation powder.

ADASUVE is a drug-device combination product that delivers the antipsychotic, loxapine, by oral inhalation. ADASUVE has been approved by the US Food and Drug Administration (FDA) for the acute treatment of agitation associated with schizophrenia or bipolar I disorder in adults. FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure that the benefits of treatment outweigh the risk of bronchospasm in patients treated with ADASUVE.

ADASUVE is not available in an outpatient setting. If you are an outpatient provider, you are receiving this letter because ADASUVE may be, or may have been, administered to one of your patients in an enrolled healthcare facility. **Enrolled healthcare facilities, such as an acute care or inpatient setting, must have immediate on-site access to equipment and personnel trained to manage acute bronchospasm, including advanced airway management, eg, intubation and mechanical ventilation.** (See below for more facility enrollment requirements.)

It is important that anyone caring for patients treated with ADASUVE be aware of the risk of bronchospasm after administration.

## Risk of Bronchospasm With ADASUVE®

- 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 diseases associated with bronchospasm are at increased risk of bronchospasm
- 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
- ADASUVE administration is limited to a single dose per patient within a 24-hour period

## Other Safety Information

- ADASUVE is also contraindicated in patients with hypersensitivity to loxapine or amoxapine (eg, serious skin reaction)
- 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



## To Administer ADASUVE<sup>®</sup>, Healthcare Facilities Must Enroll in the ADASUVE REMS Program

ADASUVE can only be administered in healthcare facilities that are enrolled in the ADASUVE REMS Program. To enroll in the ADASUVE REMS Program, a healthcare facility must have the following:

- Immediate access on-site to equipment and personnel trained to provide advanced airway management, including intubation and mechanical ventilation
- Immediate access to a metered-dose inhaled and nebulized form of a short-acting beta-agonist bronchodilator (eg, albuterol)
- Established policies, procedures or order sets in place to comply with the necessary screening and monitoring requirements of the ADASUVE REMS Program

Staff who prescribe, dispense, or administer ADASUVE, or monitor patients after receiving ADASUVE, must be trained on the safe use of ADASUVE via the ADASUVE REMS Education Program. The REMS Education Program is available as an in-service, conducted at enrolled healthcare facilities, or can be completed online.

**If you would like more information please call 855-755-0492 or visit the website at [www.adasuverems.com](http://www.adasuverems.com).**

### Adverse Event Reporting

Healthcare professionals should report suspected adverse events associated with ADASUVE to Teva Pharmaceuticals at 888-483-8279 (888-4TEVA-RX). In addition, adverse event reports may also be reported to the FDA MedWatch Reporting System by the following methods:

- Online at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm) or
- Phone at **1-800-FDA-1088**

Sincerely,

Enclosure: ADASUVE Full Prescribing Information