Steps for Safe Use of ADASUVE®

- 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 (eg, 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 patient/caregiver on potential for bronchospasm that may occur after dosing and the need to report symptoms immediately
- Monitor patients every 15 minutes for at least 1 hour after treatment for signs or symptoms of bronchospasm, including chest auscultation
- Ask patient every 15 minutes about any difficulty breathing
- Treat bronchospasm with an inhaled short-acting beta-agonist bronchodilator (eg, albuterol)
- If medically necessary, provide additional therapy for bronchospasm per asthma guidelines, including intubation and mechanical ventilation as needed
Reporting Adverse Events Associated with ADASUVE®

Healthcare professionals should understand the importance of reporting events of bronchospasm that require intubation or other advanced airway management, in addition to any fatalities that occur following ADASUVE treatment.

Suspected adverse events may be reported by the following methods:

- Teva Pharmaceuticals at 888-483-8279 (888-4TEVA-RX)
- FDA at 1-800-FDA-1088
- FDA at www.fda.gov/medwatch/report.htm
Patient Counseling

Discuss the benefits and risks associated with ADASUVE® treatment with patients and their caregivers.

Helping Patients and Caregivers Understand Risks

- Explain that certain patients may have bronchospasm after using ADASUVE
- Ask patients to tell you if they are currently taking medications to treat asthma, COPD, other breathing problems
- Inform patients of other common side effects that may occur with ADASUVE (taste and sleepiness)
- Inform patients of other serious side effects that can occur with antipsychotics, in general

Helping Patients Report Signs / Symptoms of Bronchospasm

- Ask patients to tell you immediately if they experience:
  - Difficulty breathing
  - Chest tightness
  - Wheezing
- Tell patients you have a medicine available to treat breathing problems that might occur
Administration of ADASUVE®

• ADASUVE is only administered by oral inhalation

• ADASUVE must be administered only by a healthcare professional, in an enrolled healthcare facility

Required Examination Prior to Dosing:

• Prior to administering ADASUVE, screen all patients for:
  – Current use of medications to treat asthma or COPD
  – History of asthma, COPD or other pulmonary disease
  – 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 product is then ready for use
- The indicator light turns off after the patient inhales. This indicates the dose has been delivered
- If the indicator light does NOT turn off, the dose has NOT been delivered

The pictures below show the important features of the ADASUVE product

(both sides shown)
ADASUVE®: Important Administration Instructions

Before administering ADASUVE:

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 tab to prevent automatic deactivation of the product.

   The green light will turn off, indicating that the inhaler is not usable. Discard the inhaler after one use.
ADASUVE®: Important Administration Instructions

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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.
ADASUVE®: Important Administration Instructions

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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.
ADASUVE®: Monitoring to Assess Safety

- Monitor the patient for signs or symptoms of bronchospasm after ADASUVE administration.
- Perform a physical examination, including chest auscultation, at least every 15 minutes for at least one hour after ADASUVE administration.
How to Enroll in the ADASUVE® REMS Program

• **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 enrolling include having:
  - Immediate access on-site to equipment and personnel trained to provide advanced airway management, including intubation and mechanical ventilation
  - Immediate access on-site to a metered-dose inhaled and nebulized form of a short-acting beta-agonist bronchodilator (eg, albuterol)
  - Healthcare providers within the facility (prescribers, nurses, monitoring staff, or pharmacists) who are trained on safe use of ADASUVE using the ADASUVE Education Program
  - Procedures, protocol and / or order sets guiding safe use of ADASUVE

Reference ID: 3419276
Procedures, Protocols, Order Sets for Safe Use of ADASUVE®

Procedures, protocols and / or order sets to ensure the following:

• Patients are screened, prior to treatment with ADASUVE:
  – for a history of pulmonary disease
  – for acute respiratory signs and symptoms by physical exam, including taking vital signs and chest auscultation
  – inquiring if patient is taking medication to treat asthma or COPD

• Patients are monitored at least every 15 minutes for a minimum of 1 hour following treatment with ADASUVE for signs and symptoms of bronchospasm
  – Taking vital signs
  – Chest auscultation

• Administration of ADASUVE is limited to one dose per patient within 24 hours
Designate an Authorized Healthcare Facility Representative

For each facility, an authorized healthcare facility representative is required to:

• Review the *ADASUVE® Education Program*

• Complete and sign the *Healthcare Facility Enrollment Information and Form*
  – Acknowledging that the enrolled healthcare facility meets specific requirements

• Healthcare Facility Representative:
  – May be a Pharmacist or another healthcare professional with appropriate level of responsibility within the facility
  – Authorized to act on behalf of the facility
Authorized Healthcare Facility Representative Actions

• Review the *Healthcare Facility Enrollment Information and Form* to become familiar with the enrollment requirements
• Review the *ADASUVE REMS Education Program* to become familiar with safe use conditions for ADASUVE
• Complete and sign the *Healthcare Facility Enrollment Form*
• Submit the completed form on-line, via fax, via email

The *Healthcare Facility Enrollment Information and Form* are available at [www.adasuverems.com](http://www.adasuverems.com) or by calling 855-755-0492

Reference ID: 3419276
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 benefits, risks, and safe use of ADASUVE
   – Information on healthcare facility enrollment requirements of the ADASUVE REMS Program
Other Resources Available at www.adasuverems.com

- *Dear Healthcare Professional Letter*
- *Healthcare Facility Enrollment Information and Form*
- Full Prescribing Information
- ADASUVE® Instructions for Use
- ADASUVE® Medication Guide
ADASUVE® Education Program Summary

At the end of this education program, you should understand:

• ADASUVE REMS Program Information
  – The ADASUVE REMS Program is necessary to mitigate the risk of bronchospasm that has the potential to cause respiratory distress and respiratory arrest

• Important safety information
  – ADASUVE can cause bronchospasm
  – Patients with active airways disease (asthma, COPD) are at increased risk of bronchospasm after dosing with ADASUVE
  – It is important to report events of bronchospasm that require intubation or other advanced airway management, in addition to any fatalities, that occur following ADASUVE treatment
  – Administer only a single dose of ADASUVE per patient within any 24-hour period
ADASUVE® Education Program Summary

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• How to use ADASUVE safely
  – SCREEN patients to identify and select appropriate ADASUVE patients
  – OBSERVE and MONITOR patients every 15 minutes for at least 1 hour after ADASUVE treatment
  – MANAGE bronchospasm with an inhaled short-acting beta-agonist bronchodilator or if necessary, with advanced airway equipment

• How to enroll in the ADASUVE REMS Program
  – A healthcare facility must meet specific requirements including immediate access on-site to equipment and personnel trained to provide advanced airway management, including intubation and mechanical ventilation
  – For each facility, an authorized healthcare facility representative is required to complete and sign the Healthcare Facility Enrollment Information and Form acknowledging that the enrolled healthcare facility meets specific requirements
  – Find more information at www.adasuverems.com