ADASUVE Website Screen Captures

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1. Home Page

ADASUVE® REMS Program

ADASUVE is a drug-device combination product that delivers an aerosol of the antipsychotic agent loxapine in a single 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.

The FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary for ADASUVE to ensure that the benefits of treatment outweigh the risks of bronchosperm.

The purpose of the ADASUVE REMS Program is to mitigate the risk of bronchosperm that has the potential to lead to respiratory distress and respiratory arrest.

In order to mitigate the risk, the ADASUVE REMS Program requires that ADASUVE is only administered in enrolled healthcare facilities with immediate access on site to supplies and personnel trained to manage acute bronchosperm and ready access to emergency response services.

In addition, the REMS Program will inform healthcare professionals about:

- The risk of bronchosperm after ADASUVE administration
- Appropriate patient selection
- Monitoring patients after ADASUVE administration
- Management of bronchosperm, if it occurs

Important Safety Information About ADASUVE

Risk of Bronchosperm

ADASUVE can cause bronchosperm 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 bronchosperm and ready access to emergency response services. Facilities must have a short-acting bronchodilator (e.g., albuterol) and a nebulizer and nebulizer solution, for the immediate treatment of bronchosperm.

ADASUVE is contraindicated in patients with a current diagnosis or history of asthma, chronic obstructive pulmonary disease (COPD), or other lung disease associated with bronchosperm because they are at increased risk of bronchosperm.

ADASUVE is also contraindicated in patients with acute respiratory signs/symptoms (e.g., wheezing) or who are currently taking medications to treat airflow disease, such as asthma or COPD.

ADASUVE is contraindicated in patients with a history of bronchosperm following ADASUVE treatment.

Prior to administering ADASUVE, screen patients regarding a current diagnosis or 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 bronchosperm following treatment with ADASUVE.

The Use of ADASUVE Should Be Accompanied by a 4-step Process: Screening, Counseling, Monitoring, and Management

Steps for Safe Use of ADASUVE

1. SCREEN
   - Ask if patient is taking medication to treat asthma or COPD and check medical records
   - Ask if patient has a current diagnosis or history of asthma, COPD or other lung disease and check medical record
   - 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 bronchosperm; or with current use of medications to treat airflow disease, such as asthma or COPD

2. COUNSEL
   - Counsel/patient/caregiver on potential for bronchosperm that may occur after dosing and the need for them to report signs immediately
   - Monitor patient every 15 minutes for at least 1 hour after treatment for signs and symptoms of bronchosperm including chest auscultation
   - Ask patient every 15 minutes about any difficulty breathing

3. MONITOR
   - Treat bronchosperm with an inhaled short-acting beta-agonist bronchodilator (e.g., albuterol)
   - If medically necessary, provide additional therapy for bronchosperm per asthma guidelines

These risks do not constitute a complete list of all the risks associated with ADASUVE. Please see the Prescribing Information, including Boxed Warning, for more information regarding the risks associated with ADASUVE.
2. REMS Program Enrollment Page

ADASUVE® REMS Program Enrollment

- Enrolls in ADASUVE REMS Program
- Authorized healthcare facility representative attests to certain criteria required for receipt of ADASUVE order

CLICK HERE TO ENROLL

ADASUVE Healthcare Facility Enrollment

ADASUVE will be dispensed only to patients in healthcare facilities that are enrolled in the ADASUVE REMS Program.

Authorized Healthcare Facility Representative

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

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 bronchosspasm 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 bronchosspasm.
- Medical/psychiatric (physicians, nurses, etc.) staff on site at all times (24 hours a day/7 days a week) trained to manage acute bronchosspasm.
- 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 1 hour following treatment with ADASUVE for signs and symptoms of bronchosspasm, 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 the safe use of ADASUVE using the ADASUVE Education Program

These risks do not constitute a complete list of all the risks associated with ADASUVE. Please see the Prescribing Information, including Boxed Warnings, for more information regarding the risks associated with ADASUVE.
3. ADASUVE Education Program Page

The ADASUVE 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. It ensures they understand the REMS Program requirements, ADASUVE product information, important Safety Information, how to use ADASUVE safely, and how to enroll in the ADASUVE REMS Program.

4. Healthcare Provider Brochure

The Healthcare Provider Brochure contains information about ADASUVE, as well as information on healthcare facility enrollment requirements of the ADASUVE REMS Program.

To order the ADASUVE Healthcare Provider Brochure, contact Galen at 855-755-0492.
5. Safe Use of ADASUVE

Steps for Safe Use of ADASUVE

A healthcare facility that wants to administer ADASUVE must enroll in the ADASUVE REMS Program, and the Steps for Safe Use of ADASUVE poster should then be posted where ADASUVE is administered within the enrolled healthcare facility.

ADASUVE Order Set/Protocol Template

The Order Set/Protocol Template should be used as a guideline for developing procedures, protocols, and/or order sets around the use of ADASUVE to ensure that REMS requirements are being met.
6. ADASUVE Instructions for Use

ADASUVE is only administered by oral inhalation and must be administered only by a healthcare professional in an enrolled healthcare facility.

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Click here to see Prescribing Information, including Boxed Warning.
7. Access your Account
8. Request Username

Please enter your credentials in the space provided. Your Username will be sent to your registered email address with the ADASUVE REMS Program.

First Name

Last Name

Email Address

Submit

For assistance, please contact the ADASUVE REMS Program at 855.755.0492

GALEN
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Click here to see Prescribing Information, including Boxed Warning.
9. Request Password

Please enter your Username in the space provided. Your Username is the ID you established when creating your account and this ID was also sent to you upon completion of enrollment in the ADASUVE REMS Program.

Username

Email Address

Submit

For assistance, please contact the ADASUVE REMS Program at 855-755-0492

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Click here to see Prescribing Information, including Boxed Warning.
10. Account Information