ADASUVE REMS Website

ADASUVE REMS Home Page ................................................................. 2
Contact Us Page .................................................................................. 3
Healthcare Setting Landing Page .............................................................. 4
Healthcare Setting Online Enrollment Page .................................................. 5
Healthcare Setting Online Enrollment Page with a Second Healthcare Setting Added .......................... 6
What is the ADASUVE REMS?

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 bronchospasm.

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

Only healthcare settings certified in the ADASUVE REMS may dispense ADASUVE.
Contact the ADASUVE REMS Call Center

Phone
☎ 855-755-0492

Fax
fax 855-755-0493
Healthcare Setting

Only healthcare settings certified in the ADASUVE REMS may dispense ADASUVE.

To become certified to dispense:

1. **Site Requirements**
   Have immediate access to supplies and personnel competent in the management of acute bronchospasm including: a short-acting bronchodilator (e.g., albuterol), delivered by inhaler (with spacer) or nebulizer, and access to emergency assistance for symptoms that require immediate medical attention.

2. **Designate an Authorized Representative**
   Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the ADASUVE REMS on behalf of the healthcare setting.

3. **Review the Healthcare Setting Guide**
   Have the authorized representative review the Education Program for Healthcare Settings.

4. **Complete the Healthcare Setting Enrollment Form**
   Have the authorized representative enroll in the Adasuve REMS by completing the Healthcare Setting Enrollment Form and submitting it to the Adasuve REMS.

5. **Establish Processes and Procedures**
   Establish processes and procedures to:
   - assess the patient for respiratory abnormalities before administration by medical history, medication history, and chest auscultation,
   - monitor the patient for a minimum of 1 hour after administration for bronchospasm,
   - provide that no more than a single dose of ADASUVE is administered within a 24-hour period, and
   - provide that ADASUVE is not dispensed outside of the certified healthcare setting.
Healthcare Setting Enrollment

Healthcare Setting Information (*) indicates required field

Healthcare Setting Name

Healthcare Setting Name

Healthcare Setting NPI #

Healthcare Setting NPI #

Setting Type

Medical Hospital Psychiatric Hospital Other

Setting Address

Setting Address

City

City

State

State

Zip Code

Zip Code

Phone

Fax

(999) 999-9999 (999) 999-9999

Preferred communication method

Email Fax

Authorized/Representative Responsibilities

As an authorized representative for the healthcare setting:

1. I have reviewed the Education Program for Healthcare Settings.
2. I meet established processes and procedures for:
   - Assess the patient for respiratory abnormalities before administration (by medical and medication history, and chest auscultation).
   - Monitor the patient for a minimum of 1 hour after administration for bronchospasm.
   - Ensure no more than a single dose of ADASUVE is administered within a 24-hour period.
   - Ensure ADASUVE is not dispensed outside of the certified healthcare setting.
3. My healthcare setting has immediate access to supplies and personnel onsite competent in the management of acute bronchospasm including:
   - a short-acting bronchodilator (e.g., albuterol), delivered by inhaler (with spacer) or nebulizer and access to emergency assistance for symptoms that require immediate medical attention.

On behalf of the healthcare setting, we must comply with the following REMS requirements:

Before administering:

- Assess the patient’s health status for a current diagnosis or history of asthma, chronic obstructive pulmonary disease (COPD) and other lung diseases associated with bronchospasm, acute respiratory signs and symptoms (e.g., wheezing), and current use of medications to treat airway disease such as asthma or COPD.
- Assess the patient’s health status for respiratory abnormalities by chest auscultation.

After administering, for a minimum of 1 hour:

- Assess the patient’s health status for signs and symptoms of bronchospasm.

During treatment, within a 24-hour period:

- Dispense no more than a single dose per patient.

At all times:

- Do not dispense ADASUVE for use outside of the certified healthcare setting.
- Report any adverse events or bronchospasm that occur following ADASUVE treatment to the ADASUVE REMS.
- Label each vial, dose, or package of ADASUVE with all appropriate documentation that all processes and procedures are in place and being followed.
- This includes all requirements as stated above.

To maintain certification to dispense:

- Have any new Authorized/Representative enroll in the ADASUVE REMS by completing the Healthcare Setting Enrollment Form and submitting to the ADASUVE REMS.

I authorize the above signature to be the legally binding equivalent of my handwritten signature.

Sign Type signature

Please use your mouse or stylus to sign below

Sign

Reference ID: 4928289
Healthcare Setting Enrollment

Healthcare Setting Information (*) indicates required field

Healthcare Setting Name*
MEMORIAL HOSPITAL

Healthcare Setting NPI #
1871547570

Healthcare Setting DEA #
B861235341

Setting Type
- Medical Hospital
- Psychiatric Hospital
- Other

Setting Address

City

State

ZIP Code

Phone

Fax

Add Another Healthcare Setting Location

Healthcare Setting Authorized Representative (*) indicates required field

First Name*

Last Name*

Position/Title*

Preferred communication method
- Email
- Fax
Authorized Representative Responsibilities

As an authorized representative for the healthcare setting:

- I have reviewed the Education Program for Healthcare Settings.
- I must establish processes and procedures to:
  1. assess the patient for respiratory abnormalities before administration (by medical and medication history, and chest auscultation),
  2. monitor the patient for a minimum of 1 hour after administration for bronchospasm,
  3. ensure no more than a single dose of ADASUVE is administered within a 24-hour period,
  4. ensure ADASUVE is not dispensed outside of the certified healthcare setting.
- My healthcare setting has immediate access to supplies and personnel onsite competent in the management of acute bronchospasm including: a short-acting bronchodilator (e.g., albuterol), delivered by inhaler (with spacer) or nebulizer and access to emergency assistance for symptoms that require immediate medical attention.

On behalf of the healthcare setting, we must comply with the following REMS requirements:

Before administering:

- Assess the patient’s health status for a current diagnosis or history of asthma, chronic obstructive pulmonary disease (COPD) and other lung diseases associated with bronchospasm, acute respiratory signs and symptoms (e.g., wheezing), and current use of medications to treat airway disease such as asthma or COPD.
- Assess the patient’s health status for respiratory abnormalities by chest auscultation.

After administering, for a minimum of 1 hour:

- Assess the patient’s health status for signs and symptoms of bronchospasm.

During treatment, within a 24-hour period:

- Dispense no more than a single dose per patient.

At all times:

- Not dispense ADASUVE for use outside of the certified healthcare setting.
- Report any adverse events of bronchospasm that occur following ADASUVE treatment to the ADASUVE REMS.
- Not distribute, transfer, loan, or sell ADASUVE. Maintain appropriate documentation that all processes and procedures are in place and are being followed.
- Comply with audits by Alexza Pharmaceuticals, Inc., or a third party acting on behalf of Alexza Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and are being followed.

To maintain certification to dispense:

- Have any new Authorized Representative enroll in the ADASUVE REMS by completing the Healthcare Setting Enrollment Form and submitting to the ADASUVE REMS.

Please use your mouse or stylus to sign below

I authorize the above signature to be the legally binding equivalent of my handwritten signature.