

ADASUVE Website Screen Captures

ADASUVE REMS Program

Table of Contents

1.	Home Page.....	3
2.	REMS Program Enrollment Page	4
3.	ADASUVE Education Program Page.....	5
4.	Healthcare Provider Brochure	5
5.	Safe Use of ADASUVE	6
6.	ADASUVE Instructions for Use.....	7
7.	Access your Account.....	8
8.	Request Username	9
9.	Request Password	10
10.	Account Information	11

1. Home Page



REMS Program Enrollment

ADASUVE Education Program

Healthcare Provider Brochure

Safe Use of ADASUVE

ADASUVE Instructions for Use

Sign in

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 in adults.

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 Program is to mitigate the risk of bronchospasm 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 bronchospasm, and ready access to emergency response services.

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

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

Click here to see the **REMS Program Enrollment Information for Healthcare Facilities**

Click the links below to see the **Materials for Healthcare Professionals:**

- Healthcare Provider Brochure
- Steps for Safe Use of ADASUVE
- ADASUVE Education Program
- ADASUVE Instructions for Use
- ADASUVE Order Set/Protocol Template

Important Safety Information About ADASUVE

Risk of Bronchospasm

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

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

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

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

Prior to administering ADASUVE, screen patients regarding a current diagnosis or history of symptoms of asthma, COPD and other lung diseases, and examine (including chest auscultation) patients for respiratory signs. Monitor for signs and symptoms of bronchospasm following treatment with ADASUVE.

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

Steps for Safe Use of ADASUVE	
<p>SCREEN</p>	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 (e.g., wheezing)
<p>COUNSEL</p>	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 for them to report symptoms immediately
<p>MONITOR</p>	Monitor patient every 15 minutes for at least 1 hour after treatment for signs and symptoms of bronchospasm including chest auscultation
	Ask patient every 15 minutes about any difficulty breathing
<p>MANAGE</p>	Treat bronchospasm with an inhaled short-acting beta-agonist bronchodilator (e.g., albuterol)
	If medically necessary, provide additional therapy for bronchospasm 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.



©2017 Galen US Inc.
All rights reserved. August 2017.

Site Map | Terms of Use | Privacy Policy | Contact Us



Click here to see Prescribing Information, including Boxed Warning.

2. REMS Program Enrollment Page



[Prescribing Information](#) | [Medication Guide](#) | [Contact Us](#)

REMS Program
Enrollment

ADASUVE
Education Program

Healthcare
Provider Brochure

Safe Use
of ADASUVE

ADASUVE
Instructions for Use

[Sign in](#)

ADASUVE® REMS Program Enrollment

HEALTHCARE
FACILITY

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

[CLICK HERE TO ENROLL](#)

[Click here to enroll as a Healthcare Facility in the ADASUVE REMS Program](#)

Click on a link below to view, print or order the corresponding material intended for healthcare professionals in enrolled Healthcare Facilities:

[Schedule ADASUVE Education Program In-service](#)

[View or print ADASUVE Education Program online](#)

[View, print, or order Steps for Safe Use of ADASUVE](#)

[View or print Healthcare Facility Enrollment Information Form](#)

[View or print ADASUVE Order Set/ Protocol Template](#)

To order any of the above materials, contact Galen at 855-755-0492

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 bronchospasm 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 bronchospasm.
- Medical/psychiatric (physicians, nurses, etc.) staff on site at all times (24 hours a day/7 days a week) trained to manage acute bronchospasm.
- 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 bronchospasm, 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 Warning, for more information regarding the risks associated with ADASUVE.

GALEN

©2017 Galen US Inc.
All rights reserved. August 2017.

[Site Map](#) | [Terms of Use](#) | [Privacy Policy](#) | [Contact Us](#)

[Click here to see Prescribing Information, including Boxed Warning.](#)



3. ADASUVE Education Program Page

adasuve
(loxapine) inhalation powder

Prescribing Information | Medication Guide | Contact Us

REMS Program Enrollment | **ADASUVE Education Program** | Healthcare Provider Brochure | Safe Use of ADASUVE | ADASUVE Instructions for Use

[Sign in](#)

ADASUVE Education Program

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.

Download the ADASUVE Education Program

To schedule an ADASUVE Education Program In-Service, call 855-755-0492

GALEN ©2017 Galen US Inc. All rights reserved. August 2017.

Site Map | Terms of Use | Privacy Policy | Contact Us

[Click here to see Prescribing Information, including Boxed Warning.](#)

4. Healthcare Provider Brochure

adasuve
(loxapine) inhalation powder

Prescribing Information | Medication Guide | Contact Us

REMS Program Enrollment | ADASUVE Education Program | **Healthcare Provider Brochure** | Safe Use of ADASUVE | ADASUVE Instructions for Use

[Sign in](#)

ADASUVE 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.

Download the ADASUVE Healthcare Provider Brochure

To order the ADASUVE Healthcare Provider Brochure, contact Galen at 855-755-0492

GALEN ©2017 Galen US Inc. All rights reserved. August 2017.

Site Map | Terms of Use | Privacy Policy | Contact Us

[Click here to see Prescribing Information, including Boxed Warning.](#)

5. Safe Use of ADASUVE



[Prescribing Information](#) | [Medication Guide](#) | [Contact Us](#)

[REMS Program Enrollment](#)

[ADASUVE Education Program](#)

[Healthcare Provider Brochure](#)

[Safe Use of ADASUVE](#)

[ADASUVE Instructions for Use](#)

[Sign in](#)

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.



[Download the Steps for Safe Use of ADASUVE](#)

To order Steps for Safe Use of ADASUVE, call 855-755-0492

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.



[Download the ADASUVE Order Set/Protocol Template](#)

To order the ADASUVE Order Set/Protocol Template, call 855-755-0492

GALEN

©2017 Galen US Inc.
All rights reserved. August 2017.

[Site Map](#) | [Terms of Use](#) | [Privacy Policy](#) | [Contact Us](#)

[Click here to see Prescribing Information, including Boxed Warning.](#)



6. ADASUVE Instructions for Use



[Prescribing Information](#) | [Medication Guide](#) | [Contact Us](#)

[REMS Program Enrollment](#) | [ADASUVE Education Program](#) | [Healthcare Provider Brochure](#) | [Safe Use of ADASUVE](#) | **ADASUVE Instructions for Use**

[Sign in](#)

ADASUVE Instructions for Use

[Download the 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.



GALEN ©2017 Galen US Inc. All rights reserved. August 2017.

[Site Map](#) | [Terms of Use](#) | [Privacy Policy](#) | [Contact Us](#)

[Click here to see Prescribing Information, including Boxed Warning.](#)



7. Access your Account

The screenshot shows the Adasuve website's account access page. At the top left is the Adasuve logo (toxapine) Inhalation powder. To the right are links for Prescribing Information, Medication Guide, and Contact Us. Below this is a navigation bar with buttons for REMS Program Enrollment, ADASUVE Education Program, Healthcare Provider Brochure, Safe Use of ADASUVE, and ADASUVE Instructions for Use. A Sign in button is located on the right side of the navigation bar. The main content area is titled "Access your Account" and contains a login form with fields for Username and Password, a Sign in button, and links for Need an Account?, Forgot Username?, and Forgot Password?. Below the form is a text line: "For assistance, please contact the ADASUVE REMS Program at 855-755-0492". The footer includes the GALEN logo, copyright information for Galen US Inc. (2017), and links for Site Map, Terms of Use, Privacy Policy, and Contact Us. A blue banner at the bottom contains a link to see Prescribing Information, including Boxed Warning, and an image of the Adasuve inhalation powder container.

adasuve[®]
(toxapine) Inhalation powder

Prescribing Information | Medication Guide | Contact Us

REMS Program Enrollment | ADASUVE Education Program | Healthcare Provider Brochure | Safe Use of ADASUVE | ADASUVE Instructions for Use

[Sign in](#)

Access your Account

Username

Password

[Need an Account?](#) [Forgot Username?](#) [Forgot Password?](#) [Sign in](#)

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

GALEN ©2017 Galen US Inc. All rights reserved. August 2017.

[Site Map](#) | [Terms of Use](#) | [Privacy Policy](#) | [Contact Us](#)

[Click here to see Prescribing Information, including Boxed Warning.](#)



8. Request Username

[Prescribing Information](#) | [Medication Guide](#) | [Contact Us](#)

[REMS Program Enrollment](#) | [ADASUVE Education Program](#) | [Healthcare Provider Brochure](#) | [Safe Use of ADASUVE](#) | [ADASUVE Instructions for Use](#)

[Sign in](#)

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

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

 ©2017 Galen US Inc.
All rights reserved. August 2017.

[Site Map](#) | [Terms of Use](#) | [Privacy Policy](#) | [Contact Us](#)



[Click here to see Prescribing Information, including Boxed Warning.](#)

9. Request Password

[Prescribing Information](#) | [Medication Guide](#) | [Contact Us](#)

[REMS Program Enrollment](#) | [ADASUVE Education Program](#) | [Healthcare Provider Brochure](#) | [Safe Use of ADASUVE](#) | [ADASUVE Instructions for Use](#)

[Sign in](#)

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



©2017 Galen US Inc.
All rights reserved. August 2017.

[Site Map](#) | [Terms of Use](#) | [Privacy Policy](#) | [Contact Us](#)



[Click here to see Prescribing Information, including Boxed Warning.](#)

10. Account Information



[Prescribing Information](#) | [Medication Guide](#) | [Contact Us](#)

[REMS Program Enrollment](#) | [ADASUVE Education Program](#) | [Healthcare Provider Brochure](#) | [Safe Use of ADASUVE](#) | [ADASUVE Instructions for Use](#)

[Registration](#) | [Enrollment Form](#) | [Attestation](#) | [My Activity](#) | [Sign in](#)

Account Information

First Name

Last Name

Email Address

Enrollment ID
(optional)
(If you enrolled via fax, please enter your enrollment confirmation ID.)

Username

Use Email Address as Username

Password
(Your new password must be at least eight (8) characters in length and contain at least one letter and one number.)

Confirm Password

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

GALEN ©2017 Galen US Inc.
All rights reserved. August 2017.

[Site Map](#) | [Terms of Use](#) | [Privacy Policy](#) | [Contact Us](#)

[Click here to see Prescribing Information, including Boxed Warning.](#)

