HOW TO ENROLL IN THE ADASUVE® REMS PROGRAM
(Risk Evaluation and Mitigation Strategy)

adasuve®
(loxapine) inhalation powder

HEALTHCARE FACILITY ENROLLMENT INFORMATION

ADASUVE is only distributed to certified healthcare settings (HCS) through a restricted distribution system. A healthcare facility (HCF) that wants to administer ADASUVE must enroll in the ADASUVE REMS Program to order and receive ADASUVE.

3 STEPS TO HEALTHCARE FACILITY ENROLLMENT

For each healthcare facility, an ***authorized healthcare facility representative*** is required to complete and sign the *Healthcare Facility Enrollment Form* acknowledging that the enrolled HCF 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.

REVIEW

The authorized healthcare facility representative must review the following:

- *Healthcare Facility Enrollment Form* to become familiar with the enrollment requirements for healthcare facilities
- *ADASUVE REMS Education Program* to become familiar with the safe use conditions for ADASUVE

COMPLETE AND SIGN

The healthcare facility representative completes the *Healthcare Facility Enrollment Form* online at www.adasuverems.com/enrollment, or prints the form and then completes and signs it.

By signing the form, the representative is attesting that the healthcare facility will meet all the ADASUVE REMS Program requirements prior to ordering ADASUVE.

SUBMIT

If the form was completed online, follow the instructions to submit online.

OR

Submit completed, signed form via fax at: 855-755-0493

OR

Scan completed, signed form and submit via e-mail at: Enrollment@AdasuveREMSProgram.com

Note Healthcare facilities must re-enroll every 3 years. You will be notified by fax or e-mail 60 days prior to your re-enrollment date.

ORDERING ADASUVE®

- Once the completed enrollment form is received by the ADASUVE REMS Program, it will be entered into the ADASUVE REMS Program database, which is a secured database and is accessed only by the wholesaler/distributor and Teva Pharmaceuticals
- When you place an order for ADASUVE through your wholesaler/distributor, they will check the database to confirm that your healthcare facility is enrolled. Once enrollment is confirmed, the wholesaler/distributor is allowed to ship ADASUVE to your facility

Reference ID: 3991876

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Phone 855-755-0492 Fax 855-755-0493
www.adasuverems.com/enrollment

ADASUVE® REMS Program

HEALTHCARE FACILITY ENROLLMENT FORM

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Enrollment must be complete to order and receive ADASUVE from your wholesaler/distributor.

☐ New Enrollment ☐ Re-Enrollment (Required every 3 years)

To be enrolled in the ADASUVE REMS Program, complete this form and do one of the following:		
	Fax	**855-755-0493** (Fax both pages)
	Scan and e-mail to	**Enrollment@AdasuveREMSProgram.com**
	Submit online at	**www.adasuverems.com/enrollment**

HEALTHCARE FACILITY INFORMATION

Healthcare Facility Name _____

Facility DEA or NPI Number _____

Facility Type ☐ Medical Hospital ☐ Psychiatric Hospital ☐ Other _____

Facility Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

AUTHORIZED HEALTHCARE FACILITY REPRESENTATIVE INFORMATION

First Name _____ Last Name _____

Position/Title _____

Phone _____ Fax _____

E-mail _____

Preferred communication method ☐ E-mail ☐ Fax

HEALTHCARE FACILITY AGREEMENT

As an authorized representative for this facility, I acknowledge that:

i. I am authorized to complete enrollment on behalf of this healthcare facility.

ii. I have reviewed the ADASUVE REMS Education Program and understand that treatment with ADASUVE can cause bronchospasm that has the potential to lead to respiratory distress and respiratory arrest.

iii. I understand that 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, and patients with acute respiratory signs/symptoms (e.g. wheezing) or who are taking medications to treat airways disease, such as asthma or COPD.

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HEALTHCARE FACILITY AGREEMENT (cont'd)

iv. This 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

v. This healthcare facility must establish procedures, protocols and/or order sets that are subject to audit, to help ensure compliance with the safe use conditions required in the ADASUVE REMS including the following:

- Screening patients, prior to treatment with ADASUVE, for a current diagnosis or history of asthma, COPD and other lung disease associated with bronchospasm, acute respiratory signs or symptoms (e.g. wheezing), and current use of medications to treat airways disease such as asthma or COPD; and examine patients (including chest auscultation) for respiratory abnormalities
- Monitoring patients at least every 15 minutes for a minimum of one hour following treatment with ADASUVE for signs or symptoms of bronchospasm (i.e. vital signs and chest auscultation)
- Limiting administration of ADASUVE to a single dose per patient within a 24 hour period

vi. This healthcare facility must train relevant staff (e.g. staff involved in prescribing, dispensing or administering ADASUVE and monitoring patients after ADASUVE administration) on the safe use of ADASUVE, as described in the ADASUVE REMS Education Program. This training and ongoing training must be documented and is subject to audit.

vii. This healthcare facility must not dispense ADASUVE for outpatient use.

viii. I understand this healthcare facility must renew its enrollment in the ADASUVE REMS Program within 3 years from the date of initial enrollment, and every three years thereafter.

ix. I understand that this healthcare facility must not sell, loan or transfer any ADASUVE inventory to any other pharmacy, institution, distributor, or prescriber.

x. The representative understands the importance of reporting events of bronchospasm that require emergency response services, in addition to any fatalities that occur following ADASUVE treatment. To report suspected adverse events contact Teva Pharmaceuticals at 800-284-0062, FDA at **1-800-FDA-1088** or **www.fda.gov/medwatch/report.htm**.

I confirm that the information above is correct. I understand that this information will be used to document healthcare facilities that are eligible to receive ADASUVE. I also understand that this information may be shared with government agencies.

Authorized Healthcare Facility Representative **(Signature)** _____ Date _____

Authorized Healthcare Facility Representative **(Print)** _____ Title _____

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