

Risk Evaluation and Mitigation Strategy (REMS)

What is the DSUVIA REMS (Risk Evaluation and Mitigation Strategy)?

A REMS is a strategy to manage known or potential serious risks associated with a drug and is required by the Food and Drug Administration (FDA) to ensure the benefits of a drug outweigh its risks. **DSUVIA is intended for sublingual delivery only by a healthcare provider.** DSUVIA is available only through a restricted distribution strategy called the DSUVIA REMS in order to prevent **respiratory depression resulting from accidental exposure.**

What are the DSUVIA REMS requirements?

Healthcare settings that dispense DSUVIA must:

To become certified to dispense

1. Be able to manage acute opioid overdose, including respiratory depression.
2. Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the healthcare setting.
3. Have the Authorized Representative enroll in the REMS Program by completing the **Healthcare Setting Enrollment Form** and submitting it to the REMS Program.
4. Train all relevant staff that DSUVIA must not be dispensed for use outside of the certified healthcare setting.
5. Train all relevant staff involved in administration of DSUVIA to refer to the Directions for Use prior to administration.
6. Establish processes and procedures to verify that DSUVIA is not dispensed for use outside of the certified healthcare setting.

To maintain certification to dispense

7. Have a new Authorized Representative enroll in the REMS Program by completing the **Healthcare Setting Enrollment Form** if the Authorized Representative changes.

At all times

8. Not dispense DSUVIA for use outside the certified healthcare setting.
9. Not distribute, transfer, loan, or sell DSUVIA.
10. Maintain records of staff training.
11. Maintain records of all processes and procedures including compliance with those processes and procedures.
12. Comply with audits by AcetRx Pharmaceuticals, Inc. or a third party acting on behalf of AcetRx Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and are being followed.

DSUVIA Healthcare Setting Enrollment Form

Download and complete the enrollment form to submit it 1 of 3 ways:

- **By email:** DSUVIAREMS@acelrx.com
- **By fax:** 1-650-649-1855
- **By mail:** AcetRx Pharmaceuticals, Inc.
Attn: REMS Administrator
351 Galveston Drive
Redwood City, CA 94063

DOWNLOAD FORM

Complete and submit the enrollment form online.

ENROLL ONLINE

How does my healthcare setting become certified in the DSUVIA REMS?

Your healthcare setting must designate an Authorized Representative to coordinate the certification process and oversee implementation of and compliance with the DSUVIA REMS. To enroll your healthcare setting, the Authorized Representative must complete, sign, and submit the **Healthcare Setting Enrollment Form** to the DSUVIA REMS.

By signing the **Healthcare Setting Enrollment Form**, the Authorized Representative agrees to comply, on behalf of your healthcare setting, with the following REMS requirements:

- He/she is authorized to complete the **Healthcare Setting Enrollment Form** and submit it to the REMS Program on behalf of your healthcare setting
- Your healthcare setting is able to manage acute opioid overdose, including respiratory depression
- Your healthcare setting must not dispense DSUVIA for outpatient use
 - Train all relevant staff that DSUVIA must not be dispensed for use outside of the healthcare setting
 - Establish processes and procedures to verify that DSUVIA is not dispensed for use outside of your healthcare setting
- Your healthcare setting must train all relevant staff involved in administration of DSUVIA to read the Directions for Use prior to administering DSUVIA
- Your healthcare setting must not distribute, transfer, loan, or sell DSUVIA
- Your healthcare setting must maintain records of staff training and of all processes and procedures including compliance with those processes and procedures
- Your healthcare setting must comply with audits by AcetRx Pharmaceuticals, Inc. or a third party acting on behalf of AcetRx Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and are being followed for the DSUVIA REMS. Failure to comply may result in decertification of the healthcare setting
- If the Authorized Representative changes, your healthcare setting will have a new Authorized Representative enroll in the REMS by completing the **Healthcare Setting Enrollment Form**

Receive On-Site Medical Information

AcetRx Pharmaceuticals, Inc. will provide information on DSUVIA at certified healthcare settings upon request.



To make an appointment, call
1-855-925-8476

This phone number is also available for reporting product complaints.

Healthcare Setting Resources

DSUVIA is only available through the DSUVIA Risk Evaluation and Mitigation Strategy (REMS) developed by AcetRx. Healthcare settings must enroll in the DSUVIA REMS to become certified to dispense DSUVIA. This section includes important product information.

Product Information:

DSUVIA
Directions for Use

DOWNLOAD

Prescribing
Information

DOWNLOAD

Healthcare Setting
Enrollment Form

DOWNLOAD

Indication

DSUVIA contains sufentanil, an opioid agonist, and is indicated for use in adults in a certified medically supervised healthcare setting, such as hospitals, surgical centers, and emergency departments, for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Limitations of Use

- Not for home use or for use in children. Discontinue treatment with DSUVIA before patients leave the certified medically supervised healthcare setting.
- Not for use for more than 72 hours.
- Only to be administered by a healthcare provider.
- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve DSUVIA for use in patients for whom alternative treatment options [e.g., non-opioid analgesics or opioid combination products]:
 - Have not been tolerated, or are not expected to be tolerated,
 - Have not provided adequate analgesia, or are not expected to provide adequate analgesia.

Adverse Reaction Reporting:

AcetRx Pharmaceuticals, Inc. is committed to patient safety. To report suspected adverse reactions with DSUVIA, please contact:

AcetRx Pharmaceuticals, Inc.
1-855-925-8479

Food and Drug Administration (FDA)
1-800-FDA-1088

or visit
www.fda.gov/medwatch

DSUVIA (sufentanil sublingual tablet 30 mcg) is only available through the DSUVIA Risk Evaluation and Mitigation Strategy (REMS). DSUVIA can only be dispensed and/or administered in healthcare settings that are enrolled in the REMS.

To enroll your healthcare setting,

- 1) Designate an Authorized Representative (e.g. Pharmacy and Therapeutics Chair, Pharmacy Director, Medical Director, Medical Chief-of-Staff, Director of Nursing, etc.)
- 2) Complete, sign, and submit this **Healthcare Setting Enrollment Form** to the DSUVIA REMS.

Once your healthcare setting is officially enrolled, a notification will be provided to the Authorized Representative.

HEALTHCARE SETTING AGREEMENT

I am the Authorized Representative designated by my healthcare setting to coordinate the certification process and oversee implementation of and compliance with the REMS. By signing this form, I agree to comply, on behalf of my healthcare setting, with the following REMS requirements:

- I am authorized to complete the **Healthcare Setting Enrollment Form** and submit it to the REMS Program on behalf of this healthcare setting.
- This healthcare setting is able to manage acute opioid overdose, including respiratory depression.
- This healthcare setting must not dispense DSUVIA for outpatient use.
 - Train all relevant staff that DSUVIA must not be dispensed for use outside of this healthcare setting.
 - Establish processes and procedures to verify that DSUVIA is not dispensed for use outside of this healthcare setting.
- This healthcare setting must train all relevant staff involved in administration of DSUVIA to read the Directions for Use prior to administering DSUVIA.
- This healthcare setting must not distribute, transfer, loan, or sell DSUVIA.
- This healthcare setting must maintain records of staff training and of all processes and procedures including compliance with those processes and procedures.
- This healthcare setting must comply with audits by AcelRx Pharmaceuticals, Inc. or a third party acting on behalf of AcelRx Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and are being followed for the DSUVIA REMS. Failure to comply may result in decertification of the healthcare setting.
- If the Authorized Representative changes, this healthcare setting will have a new Authorized Representative enroll in the REMS by completing the **Healthcare Setting Enrollment Form**.

AUTHORIZED REPRESENTATIVE INFORMATION

Signature: _____ Date: _____

Printed Name, Credentials: _____ Title: _____

Phone Number: _____ Fax Number: _____

Email Address: _____ Preferred Method of Communications: EMAIL FAX

HEALTHCARE SETTING INFORMATION

Name: _____

Street Address: _____ City: _____

State: _____ ZIP: _____ DEA License Number: _____

SUBMIT BY MAIL:

AcelRx Pharmaceuticals, Inc. 351 Galveston Drive
Attn: REMS Administrator Redwood City, CA 94063

OR

BY EMAIL:

DSUVIAREMS@acelrx.com

OR

BY FAX:

1-650-649-1855

If you have any questions or require additional information or further copies of DSUVIA REMS materials, please visit www.DSUVIAREMS.com, or contact the DSUVIA REMS at:

AcelRx Pharmaceuticals, Inc.
Attn: REMS Administrator
351 Galveston Drive
Redwood City, CA 94063

Phone: 1-855-925-8476
Email: DSUVIAREMS@acelrx.com
Fax: (650) 649-1855

This form is part of an FDA-approved REMS.
For more information about DSUVIA, please see Prescribing Information, including Boxed Warnings.

Please Review & Act on These Documents



Sample Sender
REMS Enrollment Form

Please review & sign your document. To begin the process of reviewing and signing your documents, please click the button below. Signing will not be complete until you have reviewed the agreement and you have confirmed your signature.

Please review the documents below.

CONTINUE

OTHER ACTIONS ▾

DSUVIA™ REMS

Healthcare Setting Enrollment Form

DSUVIA (sufentanil sublingual tablet 30 mcg) is only available through the DSUVIA Risk Evaluation and Mitigation Strategy (REMS). DSUVIA can only be dispensed and/or administered in healthcare settings that are enrolled in the REMS.

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- This healthcare setting must train all relevant staff involved in administration of DSUVIA to read the Directions for Use prior to administering DSUVIA.
- This healthcare setting must not distribute, transfer, loan, or sell DSUVIA.
- This healthcare setting must maintain records of staff training and of all processes and procedures including compliance with those processes and procedures.
- This healthcare setting must comply with audits by AcellRx Pharmaceuticals, Inc. or a third party acting on behalf of AcellRx Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and are being followed for the DSUVIA REMS. Failure to comply may result in decertification of the healthcare setting.
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AUTHORIZED REPRESENTATIVE INFORMATION



START

DSUVIA™ REMS

Healthcare Setting Enrollment Form

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AUTHORIZED REPRESENTATIVE INFORMATION

Signature:  Date:

Printed Name, Credentials: Title:

Phone Number: Fax Number:

Email Address: Preferred Method of Communications: EMAIL FAX

HEALTHCARE SETTING INFORMATION

Name:

Street Address: City:

State: ZIP: DEA License Number:

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NEXT



START

DSUVIA™ REMS

Healthcare Setting Enrollment Form

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Attn: REMS Administrator Redwood City, CA 94063

OR

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DSUVIAREMS@acelrx.com

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BY FAX:

1-650-649-1855

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Attn: REMS Administrator
351 Galveston Drive
Redwood City, CA 94063

Phone: 1-855-925-8476
Email: DSUVIAREMS@acelrx.com
Fax: (650) 649-1855

This form is part of an FDA-approved REMS.
For more information about DSUVIA, please see Prescribing Information, including Boxed Warnings.

FINISH

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JOSHUA M LLOYD on behalf of SHARON H HERTZ
11/02/2018