

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.