Risk Evaluation and Mitigation Strategy (REMS)

What is the SUBLOCAL REMS (Risk Evaluation and Mitigation Strategy) Program?
A REMS is a strategy to manage known or potential risks associated with a drug, and is required by the FDA for certain new or changed drug labeling. If it is approved, SUBLOCAL is included in a REMS program. The REMS program is intended to ensure that the benefits of SUBLOCAL outweigh the risks. SUBLOCAL is being offered through a manufacturer distribution program under the SUBLOCAL REMS Program because of the risk of serious harm or death that could result if SUBLOCAL is misused or otherwise administered.

What are the SUBLOCAL REMS program requirements?

- All healthcare settings and pharmacies that dispense SUBLOCAL must be certified. 
- Healthcare providers, hospitalists, and patients must obtain SUBLOCAL through a manufacturer distribution program.
- SUBLOCAL should not be dispensed directly to a patient.

When healthcare settings MUST be certified to receive the SUBLOCAL REMS Program:

- All healthcare settings and pharmacies that dispense SUBLOCAL must be certified. Examples of healthcare settings include: group practices, independent practice associations, institutions, Department of Defense (DoD) facilities, Federal (Fed) facilities, local and state health departments, clinics, commercial treatment (OTP) centers, local health systems, and other healthcare settings.

How does my healthcare facility or pharmacy become certified in the SUBLOCAL REMS Program?

- Call Direct
- Designate or authorize representatives. The designated or authorized representative will ensure that the dispensing location meets the REMS requirements as set out by the manufacturer, patient, and dispensing pharmacy.
- Call Direct to set up the REMS Program.
- Complete the REMS Program
- Submit a REMS Program Certification Form.

- Complete the Enrollee Process Form.
- Complete the SUBLOCAL REMS Program Health Setting and Pharmacy Enrollment Form.
- Only one (1) form is needed per healthcare setting. A pharmacy is certified under their healthcare setting's enrollment in the SUBLOCAL REMS Program.

The SUBLOCAL REMS Program Health Setting and Pharmacy Enrollment Form contains three sections:
- Activated Representative Signature section
- Activated Representative Information section
- Healthcare Setting Information section

For the enrollee process, the activated representative must be mailed a copy. To add additional healthcare setting after the initial enrollment, you may need to fill out the Activated Representative Information section for each additional location where SUBLOCAL will be shipped with your healthcare system.

If designated a pharmacist representative, the new activated representative must complete and sign a new SUBLOCAL REMS Program Health Setting and Pharmacy Enrollment Form, including a Healthcare Setting Information section for each healthcare setting with which he or she is affiliated.

The SUBLOCAL REMS Program Health Setting and Pharmacy Enrollment Form may be completed as one of the following permitted options:

- To enroll clinics, please click here.
- For enrolled universities, please contact all required fields on the form and the University Health System’s Program Coordinator for each dispensing site, and mail the completed form to the designated healthcare setting.
- For enrollment (by email), please complete all required fields on the form and send the University Health System’s Program Coordinator for each dispensing site, and mail the completed form to the designated healthcare setting.

Implement the REMS Program

- Sublocal is dispensed directly to a healthcare provider for administration to a patient. Sublocal should not be dispensed directly to a patient.
- Remember the necessary status and processes to comply with the SUBLOCAL REMS Program.

How can certified healthcare settings obtain SUBLOCAL for potential patients?

- Pharmacy orders may be submitted to the designated healthcare setting in which the patient resides.
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How can I obtain SUBLOCAL for patients in my care?

- Through a healthcare provider for a patient's care.
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How do I notify the FDA about adverse events related to SUBLOCAL?

- Please refer to the FDA’s MedWatch Program for information on how to report adverse events. MedWatch is the FDA’s vehicle for reporting a suspected adverse reaction to a drug or biologic.
- If you believe you or anyone else is experiencing a serious adverse event, please call 1-800-FDA-1088 or visit: http://www.fda.gov/medwatch/report.htm. If you have questions, please call 1-877-237-2005.
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Risk Evaluation

What is the SUBLODAR program?

A "meeting the criteria for initiation (but not necessarily for initiation)" drug under the "inhibitor (but not necessarily for initiation)" class of drugs may indeed result in serious harm to one’s adrenal gland. The adrenal gland is responsible for the release of hormones that are necessary for the body’s function. One of these hormones is cortisol, which is responsible for the body’s response to stress. If the adrenal gland is not functioning properly, it can lead to serious health problems.

What are the requirements for the SUBLODAR program?

All patients initiating a substance must be enrolled in the SUBLODAR program. This program requires that all patients with adrenal gland function must be enrolled in the program. The patient must then be monitored by the SUBLODAR program to ensure that they are receiving the appropriate treatment.

How does this impact your health care setting or pharmacy concern associated with the SUBLODAR program?

SUBLODAR is a program that helps healthcare providers and pharmacies identify patients who may be at risk for adrenal gland dysfunction. This program is designed to help healthcare providers and pharmacies identify patients who may be at risk for adrenal gland dysfunction. The program provides a tool for healthcare providers and pharmacies to identify patients who may be at risk for adrenal gland dysfunction and to ensure that they are receiving the appropriate treatment.

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