

## Risk Evaluation and Mitigation Strategies (REMS)

*Understanding REMS with this updated listing will help your facility service your residents more effectively and quickly*

Remedi is pleased to provide you with this updated listing of medications that you may have a difficult time getting for your patient due to restricted access imposed by the FDA.

In 2007 the FDA was legally granted permission to impose restrictions on drug manufacturers to ensure optimal and safe use of some potentially dangerous medications. This Risk Evaluation and Mitigation Strategies (REMS) program was essentially designed to manage a known or potentially serious risk associated with a medication, while still providing patient access to that medication. Examples of the risks include serious infection, severe allergic reaction, liver damage, birth defects etc.

Developed by the drug sponsor and approved by the FDA, the strategies differ with each medication but can range from additional information, such as distribution of a medication guide to additional training or certifications for prescribers, pharmacies and other practitioners. Patients receiving these medications are enrolled into a registry for that drug and sometimes subject to additional laboratory monitoring or physical evaluations.

Just like not all prescribers are authorized to prescribe REMS mediated medications, not all Pharmacies are authorized to dispense them. Many pharmacies choose not participate in a program, based on the inordinate amount of time, money and effort required to dispense a medication that may only be dispensed once a year. If your resident is admitted to the facility on one of the REMS medications, the pharmacy will notify you of that and often times the family already has the knowledge about the REMS program and where to obtain the medication. If a prescriber writes a new prescription for a medication that is limited under the REMS program, your Remedi SeniorCare Pharmacist will notify you of that and make recommendations for alternatives if one is available.

If you have any questions, please contact:

- Your Remedi SeniorCare Pharmacist for more information
- Call or access the websites indicated on the guideline.

**Table 1- Medications with Restricted Access Programs.**

Medication	Indication/Use	Safety concern	Enrollment	Program details	Contact information
<b>Alglucosidase alfa (Lumizyme)</b>	Pompe disease	Rapid progression of Pompe disease in patients less than 8 years old Anaphylaxis and immune-mediated reactions	Prescriber  Patient  Healthcare facility	Lumizyme ACE program  Must complete infusion confirmation form with every administration	800-745-4447  <a href="http://www.lumizyme.com/ace/default.asp">http://www.lumizyme.com/ace/default.asp</a>
<b>Alosetron (Lotronex)</b>	Irritable bowel syndrome (IBS) in women who have failed conventional therapy	Ischemic colitis	Prescriber	Prescribing Program for Lotronex (PPL)  Rx must be handwritten Blue sticker must be affixed to Rx	<a href="http://www.lotronexppl.com/">888-423-5227 http://www.lotronexppl.com/</a>
<b>Ambrisentan (Letairis)</b>	Pulmonary hypertension	Hepatotoxicity  Teratogenic effects	Prescriber  Patient	Letairis Education and Access Program (LEAP) Distribution to patient  Monitoring of liver function and pregnancy every month	866-664-LEAP  <a href="http://www.letairisrems.com/REMS_Program.aspx">http://www.letairisrems.com/REMS_Program.aspx</a>
<b>Bosentan (Tracleer)</b>	Pulmonary hypertension	Hepatotoxicity  Teratogenic effects	Prescriber  Patient	Tracleer Access Program (T.A.P.) Distribution to patient  Monitoring of liver function and pregnancy every month	866-228-3546  <a href="http://www.tracleer.com/patient/services-and-support.asp">http://www.tracleer.com/patient/services-and-support.asp</a>
<b>Buprenorphine (Subutex)  Buprenorphine/Naloxone (Suboxone)</b>	Opioid Dependence	Abuse potential  Law requires certification of providers who treat opioid dependence	Prescriber certification	Must confirm physician certification prior to dispensing  Special DEA number used	800-BUP-CSAT  <a href="http://www.suboxone.com/hcp/certification/">http://www.suboxone.com/hcp/certification/</a>  <a href="http://www.buprenorphine.samhsa.gov/">http://www.buprenorphine.samhsa.gov/</a>
<b>Buprenorphine transdermal (Butrans)</b>	Pain	Overdose with abuse, overdose in non-opioid tolerant patients, addiction potential	Prescriber	Butrans REMS Education Program	888-726-7535  <a href="http://www.butransrems.com/">http://www.butransrems.com/</a>
<b>Clozapine (Clozaril)</b>	Schizophrenia	Neutropenia  Aplastic anemia	Prescriber  Pharmacy	Clozaril National Registry  Monitoring of WBC every 2-4 weeks  Prescriber must provide results to pharmacy before dispensing	800-448-5938  <a href="http://www.clozaril.com/hcp/tools/download_forms.jsp">http://www.clozaril.com/hcp/tools/download_forms.jsp</a> <a href="https://www.clozarilcare.com/care/Splash.jsp">https://www.clozarilcare.com/care/Splash.jsp</a>
<b>Deferasirox (Exjade)</b>	Iron Toxicity	None	Prescriber  Patient	EPASS Advantage Distribution to patient	888-90-EPASS  <a href="http://www.us.exjade.com/patient/epass-advantage.jsp">http://www.us.exjade.com/patient/epass-advantage.jsp</a>
<b>Dofetilide (Tikosyn)</b>	Atrial Fibrillation/ Atrial Flutter	QT prolongation	Prescriber education  Pharmacy	Tikosyn in Pharmacy System (T.I.P.S.) Pharmacy must verify prescriber enrollment	877-TIKOSYN  800-788-7353

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<b>Eculizumab</b>  (Soliris)	Paroxysmal nocturnal hemoglobinuria / Atypical hemolytic-uremic syndrome	Meningococcal infection	Prescriber  Patient	OneSource Safety Support Program  Distribution to office, clinic, hospital, or specialty pharmacy  Patient must receive meningococcal vaccine 2 weeks prior to therapy initiation	888-SOLIRIS  <a href="http://www.solirisrems.com/">http://www.solirisrems.com/</a>
<b>Eltrombopag</b> (Promacta)	Thrombocytopenic	Hepatotoxicity  Bone marrow reticulin/fibrosis  Thrombotic/thromboembolic events  Hematological malignancy	Prescriber Patient Pharmacy	PROMACTA CARES  Pharmacy must call program before dispensing  Must track inventory for auditing purposes	877-9PROMACTA  <a href="http://www.promactacares.com/dispense.html">http://www.promactacares.com/dispense.html</a>
<b>Fentanyl buccal</b> (Onsolis)	Pain	Overuse, abuse, addiction potential  Respiratory depression in non-opioid tolerant patients	Prescriber education	FOCUS program for Onsolis  Distribution only through authorized distributors	877-4ONSOLIS  <a href="http://www.onsolisfocus.com/index.html">http://www.onsolisfocus.com/index.html</a>
<b>Fentanyl buccal tablet</b> (Fentora)			Prescriber (outpatient) Pharmacy (outpatient or inpatient)	ACTIQ and FENTORA REMS program  Distribution only through authorized distributors	888-688-6885  <a href="https://www.actiqandfentorems.com">https://www.actiqandfentorems.com</a>
<b>Fentanyl nasal spray</b> (Lazanda)			LAZANDA REMS program  Distribution only through authorized distributors	855-841-423  <a href="https://www.lazandarems.com">https://www.lazandarems.com</a>	
<b>Fentanyl transmucosal lozenge</b> (Actiq)			ACTIQ and FENTORA REMS program  Distribution only through authorized distributors	888-688-6885  <a href="https://www.actiqandfentorems.com/">https://www.actiqandfentorems.com/</a>	
<b>Fentanyl transmucosal tablet</b> (Abstral)			ASBTRAL REMS program  Distribution only through authorized distributors	1-888-ABSTRAL  <a href="https://www.abstralrems.com">https://www.abstralrems.com</a>	
<b>Gefitinib</b> (Iressa)	Non-small cell lung cancer (NSCLC)	Lack of evidence for clinical benefit  Only for patients taking before September 2005 with clinical response	Prescriber  Patient	IRESSA Clinical Access Program  Distribution to patient	877-283-0955
<b>Hydromorphone ER</b> (Exalgo)	Pain	Overdose with abuse, overdose in non-opioid tolerant patients, addiction potential	Prescriber	Exalgo REMS Education Program	1-888-9EXALGO <a href="http://www.exalgorems.com/">http://www.exalgorems.com/</a>
<b>Isotretinoin</b>  (Accutane and other brands)	Acne, other off-label uses	Teratogenic effects	Prescriber  Patient  Pharmacy	iPLEDGE  Monthly verification of 2 negative pregnancy tests Patient must use 2 forms of contraception	866-495-0654  <a href="https://www.ipleadgeprogram.com/">https://www.ipleadgeprogram.com/</a>

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<b>Lenalidomide (Revlimid)</b>	Multiple myeloma, myelodysplastic syndrome, mantle cell lymphoma	Teratogenic effects	Prescriber  Patient  Pharmacy	RevAssist  Monthly verification of negative pregnancy tests by prescriber and pharmacy  Patient must use 2 forms of contraception	888-423-5436 <a href="http://www.revlimid.com/hcp/hcp-revassist-pre.aspx">http://www.revlimid.com/hcp/hcp-revassist-pre.aspx</a>
<b>Natalizumab (Tysabri)</b>	Crohn's disease, Multiple Sclerosis	Progressive Multifocal Leucoencephalopathy (PML)	Prescriber Patient  Pharmacy Infusion center	TOUCH Prescribing Program  Must complete pre-infusion patient checklist	800-456-2255 <a href="http://www.tysabri.com/">http://www.tysabri.com/</a>
<b>Olanzapine ER injection (Zyprexa Relprevv)</b>	Schizophrenia	Post-injection delirium/ sedation syndrome (PDSS)	Prescriber Patient Pharmacy Healthcare facility	Zyprexa Relprevv Patient Care	877-772-9390 <a href="https://www.zyprexarelprevvprogram.com/public/registration_forms.aspx">https://www.zyprexarelprevvprogram.com/public/registration_forms.aspx</a>
<b>Romiplostim (Nplate)</b>	Idiopathic thrombocytopenic purpura	Hepatotoxicity Bone marrow reticulin/fibrosis  Thrombotic / thromboembolic events Hematological malignancy	Prescriber Patient	Nplate NEXUS Program Verify enrollment prior to dispensing  Direct distribution or order from wholesaler	877-NPLATE <a href="http://www.nplatenexus.com/enrollment.html">http://www.nplatenexus.com/enrollment.html</a>
<b>Rosiglitazone (Avandia, Avandamet, Avandryl)</b>	Type 2 Diabetes	Myocardial infarction	Prescriber  Patient	Avandia-Rosiglitazone Medicines Access Program Distribution to patient	800-282-6342 <a href="https://www.avandia.com/">https://www.avandia.com/</a>
<b>Sodium oxybate (Xyrem)</b>	Cataplexy, Narcolepsy	Overuse, abuse, addiction potential	Prescriber Patient	Physician Success Program Patient Success Program Distribution to patient	866-997-3688 <a href="http://www.xyrem.com/healthcare-professionals/">http://www.xyrem.com/healthcare-professionals/</a>
<b>Tapentadol (Nucynta ER)</b>	Pain	Overdose with abuse, overdose in non-opioid tolerant patients, addiction potential	Prescriber	Nucynta ER Healthcare Professional Education Program	800-526-7736 <a href="http://www.nucyntaerems.com">http://www.nucyntaerems.com</a>
<b>Thalidomide (Thalomid)</b>	Erythema nodosum leprosum, multiple myeloma	Teratogenic effects	Prescriber  Patient Pharmacy	System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.) Program  Rx must have authorization number Pharmacy must call program before dispensing	888-423-5436 <a href="http://www.thalomid.com/steps_program.aspx">http://www.thalomid.com/steps_program.aspx</a>
<b>Vandetanib (Caprelsa)</b>	Thyroid cancer	QT prolongation	Prescriber Pharmacy	CAPRELSA REMS Program  Distribution to pharmacy, hospital, or long-term care facility	800-236-9933 <a href="http://www.caprelsarems.com/">http://www.caprelsarems.com/</a>
<b>Vigabatrin (Sabril)</b>	Refractory complex partial seizures	Irreversible vision loss	Prescriber  Patient	Support, Help and Resources for Epilepsy (SHARE) Vision must be assessed at baseline and every 3 months Distribution to patient	888-45-SHARE <a href="http://www.lundbeckshare.com/pg512_important_steps.aspx">http://www.lundbeckshare.com/pg512_important_steps.aspx</a>

**Table 2. Medications with Limited Distribution Programs.**

Medication	Indication/Use	Program details	Contact information
<b>Alpha-1 proteinase inhibitor (human) (Prolastin)</b>	Emphysema, alpha-1 proteinase inhibitor	Prolastin Direct Distribution to patient	800-305-7881 <a href="http://www.prolastin.com/5.0.0_cons_howto.aspx">http://www.prolastin.com/5.0.0_cons_howto.aspx</a>
<b>Alpha-1 proteinase inhibitor (human) (Aralast NP, Glassia)</b>	Emphysema due to alpha-1 proteinase inhibitor	Alpha-1 AATmosphere Program Distribution to patient	866-272-5278 <a href="http://www.aatmosphere.com/">http://www.aatmosphere.com/</a>
<b>Alvimopan (Entereg)</b>	Ileus prophylaxis	E.A.S.E. Program Distribution to hospital	866-4ADOLOR <a href="http://www.entereg.com/content/remss/">http://www.entereg.com/content/remss/</a>
<b>Dalfampridine (Ampyra)</b>	Multiple sclerosis	Distribution to patient	888-881-1918 <a href="http://ampyra-hcp.com/hcp/physician_resources/presc_service_requests/">http://ampyra-hcp.com/hcp/physician_resources/presc_service_requests/</a>
<b>Iloprost (Ventavis)</b>	Pulmonary arterial hypertension	PAH Pathways Distribution to patient	866-ACTELION <a href="https://www.pahpathways.com/hcp/hcp_sub_ventavis_enrollment.asp">https://www.pahpathways.com/hcp/hcp_sub_ventavis_enrollment.asp</a>
<b>Sacrosidase (Sucraid)</b>	Sucrase-isomaltase deficiency	Distribution to patient	866-740-2743 877-599-7748 (hospital distributor) <a href="http://www.sucraid.net/">http://www.sucraid.net/</a>
<b>Sorafenib (Nexavar)</b>	Renal or hepatocellular cancer	REACH Program Distribution to patient	866-NEXAVAR 800-746-6273 (hospital distributor) <a href="https://www.nexavar-us.com/scripts/pages/en/hcp/hcc/patient-support/reach-program/enrolling-in-reach/">https://www.nexavar-us.com/scripts/pages/en/hcp/hcc/patient-support/reach-program/enrolling-in-reach/</a>

**Table 3: Medications with Special Dispensing and Prescribing Requirements**

Medication	Indication/Use	Special Requirement
<b>Cisapride (Propulsid)</b>	GERD	Only available through limited-access investigational programs.
<b>Epoprostenol (Flolan)</b>	Pulmonary hypertension	Available only through specialty pharmacies
<b>Alpha 1-Proteinase Inhibitor (Zemaira)</b>	Emphysema due to alpha-1 proteinase inhibitor	Available only through specialty pharmacies
<b>Tetrabenazine (Xenazine)</b>	Huntington's Disease	Available only through specialty pharmacies
<b>Vemurafenib (Zelboraf)</b>	Malignant melanoma	Available only through specialty pharmacies