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ISMP
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Community/Ambulatory Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

Teaching patients how to measure vigabatrin oral solutions is critical to prevent errors in children

Problem: Vigabatrin is an antiseizure medication approved for adjunctive therapy for adults and pediatric patients greater than or equal to 2 years of age with refractory complex partial seizures or as monotherapy for pediatric patients 1 month to 2 years of age with infantile spasms. However, use of this medication is not without risk. Vigabatrin carries a *Boxed Warning* for permanent vision loss. This risk increases with cumulative exposure and increasing doses, but there is no dose known to be risk-free. The risk is possible during drug usage and after discontinuation. Baseline and periodic vision assessments are recommended but cannot always prevent vision damage. Once detected, vision loss is not reversible. Therefore, practitioners along with their patients must decide whether the potential benefits of therapy outweigh the potential risk of vision loss before initiating treatment.

To help manage the risk of vision loss, vigabatrin is only available through a Risk Evaluation and Mitigation Strategies (REMS) program (www.vigabatrinrems.com), which includes all formulations of the product. Providers must become REMS certified to prescribe either brand or generic vigabatrin. Outpatient and inpatient pharmacies must be certified to dispense vigabatrin and wholesalers can only distribute to certified pharmacies. Finally, patients must complete the Patient/Parent/Legal Guardian-Physician Agreement form and receive counseling from the provider regarding the benefits and risks associated with vigabatrin.

The medication is available as 500 mg tablets (**SABRIL**, **VIGADRONE**, and generics) and packets containing 500 mg of powder for oral solution (Sabril, Vigadrone, **VIGPODER**, and generics) which is dissolved in 10 mL of water to make a 50 mg/mL solution. Recently, a new ready-to-administer 100 mg/mL concentrated oral solution, **VIGAFYDE**, was approved for the treatment of infantile spasms in patients 1 month to 2 years of age. While we have not received reports of errors with this new product, we wanted to bring your attention to some safety risks we identified while reviewing the product.

Weight [kg]	Starting Dose 50 mg/kg/day	Maximum Dose 150 mg/kg/day
3	75 mg (0.75 mL) twice daily	225 mg (2.25 mL) twice daily
4	100 mg (1 mL) twice daily	300 mg (3 mL) twice daily
5	125 mg (1.25 mL) twice daily	375 mg (3.75 mL) twice daily
6	150 mg (1.5 mL) twice daily	450 mg (4.5 mL) twice daily
7	175 mg (1.75 mL) twice daily	525 mg (5.25 mL) twice daily
8	200 mg (2 mL) twice daily	600 mg (6 mL) twice daily
9	225 mg (2.25 mL) twice daily	675 mg (6.75 mL) twice daily
10	250 mg (2.5 mL) twice daily	750 mg (7.5 mL) twice daily
11	275 mg (2.75 mL) twice daily	825 (8.25 mL) twice daily
12	300 mg (3 mL) twice daily	900 (9 mL) twice daily
13	325 mg (3.25 mL) twice daily	975 mg (9.75 mL) twice daily
14	350 mg (3.5 mL) twice daily	1050 mg (10.5 mL) twice daily
15	375 mg (3.75 mL) twice daily	1125 mg (11.25 mL) twice daily
16	400 mg (4 mL) twice daily	1200 mg (12 mL) twice daily

Figure 1. The dosing table provided in the Vigafyde prescribing information provides weight-based dosing in both mg and mL doses. However, some typical oral and ENFit syringes may not have markings for some of the indicated doses (e.g., 1.25 mL).

The dosing of Vigafyde is based on the patient's weight in kilograms (kg). The initial daily dosing is 50 mg/kg/day given in two divided doses (25 mg/kg twice daily); subsequent dosing can be titrated by 25 mg/kg/day to 50 mg/kg/day increments every 3 days, up to a maximum of 150 mg/kg/day given in 2 divided doses (75 mg/kg twice daily). To help guide prescribing, the company provides a dosing table in the prescribing information (**Figure 1**). Doses are provided in both milligrams (mg) and milliliters (mL) which is helpful for providers and pharmacists to ensure the correct mg dose and corresponding dose volume is provided to the patient. However, as you can see in the table, the company has rounded

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SAFETY briefs

Wrong-patient home delivery error. We continue to receive reports about errors when prescriptions are delivered to the wrong patient's home. In one recent case, a pharmacy reported that a prescription for gabapentin, used to treat a variety of conditions including focal onset seizure and neuropathic pain, was delivered to the wrong patient. The patient took one capsule before discovering the error. In another case, a patient received a different patient's prescription bag but quickly realized it was the wrong medication. The patient called the pharmacy to report the error. The pharmacy noted that both patients had similar names and addresses. Also, the driver was feeling rushed to finish their deliveries as it was the end of the day. In both cases, the driver did not verify the patient's name, address, or date of birth. The delivery drivers returned to the patients' homes to retrieve the wrong prescriptions.

If the pharmacy uses its own delivery personnel, educate the drivers to ask the patient (or the person accepting the package) to state the patient's full name

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IMPORTANT! Read and utilize the Community/Ambulatory Care Action Agenda

Items from the **May – August 2024** issues of the ***ISMP Medication Safety Alert! Community/Ambulatory Care*** newsletters have been selected and prepared for you and your staff to stimulate discussion and collaborative action to reduce the risk of medication errors. Each item includes a brief description of the medication safety problem, a few recommendations to reduce the risk of errors, and the issue date to locate additional information. The **Action Agenda** is available as an Excel file.

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the doses to the nearest quarter of an mL. This is fine on the surface except that most commercially available oral and ENFit syringes do not have markings to measure a quarter of an mL (e.g., 1.25 mL, 1.75 mL). And, to make matters worse, the manufacturer does not provide a customized oral syringe with the product so doses can be accurately measured to these specific increments. As a result, caregivers who do not receive education and/or tools to help measure a dose accurately will either estimate the dose volume to be in between dose markings (e.g., between 1.6 and 1.8 mL markings for a 1.75 mL dose volume if using some 5 mL syringes) or draw up the medication to the closest marking. If not done appropriately (i.e., misreading the graduation mark), an over- or underdose may occur.

Another safety concern is that confusion and dosing errors could occur if patients are switched from the 500 mg packets to the ready-to-use 100 mg/mL oral solution or vice versa. While the starting (50 mg/kg/day) and maximum (150 mg/kg/day) dosing recommendations are the same for both formulations, Vigafyde is twice as concentrated (100 mg/mL) as the solution prepared with a packet (50 mg/mL). If the dose volume is not updated when changing the formulation from the packet to the oral solution, a child could receive a dose two times as much as they should (e.g., 1.5 mL [75 mg] for the packet versus 1.5 mL [150 mg] for the oral solution), increasing the risk of vision loss as this risk escalates with cumulative exposure and higher doses.

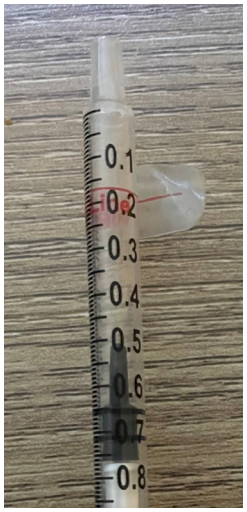

Figure 2. An example of an auxiliary label applied to an oral syringe to indicate to where to measure the prescribed medication.

Safe Practice Recommendations: Anytime there is a change in formulations (e.g., from the oral packets to the oral solution), both prescribers and pharmacists must confirm the mg dose is correct and the volume to be administered is correct based upon the product's concentration. To help caregivers administer the correct dose, pharmacies must dispense oral or ENFit syringes. The syringe must be of the most appropriate size to measure the dose (e.g., a dosing device that most closely matches the prescribed dose volume and limits the number of times the device needs to be filled to administer a single dose). For doses less than 1 mL, pharmacies should provide 1 mL oral or ENFit syringes. Pharmacists should mark the syringe to indicate the volume to be measured and administered. You may consider affixing an auxiliary label (**Figure 2**) that provides a visual clue as to where the caregiver should measure the patient's dose. Also, keep in mind that the patient instructions printed on the pharmacy label should include the dose in only the unit of measure used for administration, which in this case would be mL. Printing both the mg and mL (e.g., 1.5 mL [150 mg]) on the pharmacy label can increase the risk of confusion for the patient. Use the teach-back method to teach patients and/or caregivers how to measure and administer this medication to verify their understanding.

Cutting cloNIDine patch leads to patient harm

A children's hospital reported a case in which a prescriber advised parents to cut their child's clo**NID**ine patches in an attempt to provide a reduced dose of medication. However, clo**NID**ine patches should not be cut as this can impact the drug delivery rate and may result in patients receiving an increased dose. A clo**NID**ine overdose can result in serious toxic effects as seen in the case described below.

The prescriber ordered a clo**NID**ine transdermal system (patch) for a child to treat hypertension. The child's mom messaged the prescriber through a patient portal to notify them her child was experiencing somnolence and bradycardia. The prescriber replied to the message, instructing the mom to cut her child's clo**NID**ine patch in half as a method to reduce the dose and lessen the side effects. The following morning, the prescriber sent a follow-up message, stating not to cut the patch in half. However, the mom had already placed the cut patch on her child and was unaware the

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and address (or date of birth) and have the driver verify at least two of these identifiers against the delivery information on the package label. Consider using automation to verify addresses—requiring the driver to enter and confirm the address in the system prior to delivery, scan a barcode to confirm the address, and/or use global positioning system (GPS) location verification. If you use an external courier service, meet with them to discuss issues and errors and implement risk-reduction strategies. Collaborate with them to ensure staff are properly educated and competent, including how to verify the patient's identity and address before handing over the prescription(s). Always educate the patient to immediately open the prescription package, check the contents of each prescription container, and call the pharmacist with any concerns or questions.

Three-letter character search resulted in an error. When entering a prescription in the pharmacy computer system for **TOPROL XL** (metoprolol extended release), a beta-blocker used to treat hypertension, a pharmacy staff person typed "top" to search for the drug. They inadvertently selected topiramate, an antiseizure agent, from the drop-down list of matching drug names. Instead of entering a prescription for Toprol XL 25 mg, take one tablet by mouth daily, the prescription was entered as topiramate 25 mg, take one tablet by mouth daily. The medication error was missed during dispensing as the drug scanned "correctly" as topiramate 25 mg, matching what was entered in the computer, and the prescription was filled with the wrong medication.

If only a portion of the name is used to search for products or populate fields in electronic health record (EHR) or pharmacy computer systems, consider the entry of a minimum of the first five letters of the drug name. Of course, it is best to keep adding letters until the intended drug name appears distinct by itself. Prescribers should include the purpose of the drug on prescriptions to help ensure the correct medication is selected. Pharmacists should review the prescription

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prescriber sent a new message in the portal. The clo**NID**ine patch package does not include a warning to avoid cutting it (**Figure 1**). The child continued to experience somnolence and bradycardia, so the mom called the prescriber's office, and they instructed her to remove the patch. Unfortunately, the child's symptoms worsened over the next few hours. The parents drove the child to the emergency department (ED) but in route, he became unresponsive to sternal rub, so they called 911. An ambulance met the parents and drove the child to the ED. He was admitted for observation and fortunately, returned to baseline in less than 24 hours.

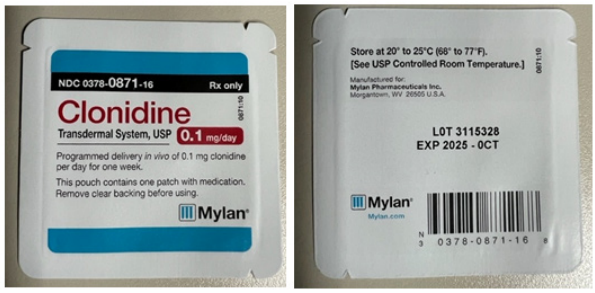

Figure 1. The front (left) and back (right) of the clo**NID**ine transdermal system package do not include a warning to not cut the patch.

We have notified the US Food and Drug Administration (FDA) and recommend that clo**NID**ine transdermal system packaging be updated to include a prominent warning to not cut the patch. Identify which patches can be safely cut and which cannot. Share the information with staff. Provide verbal and written education to patients/caregivers on the use of patches (e.g., when to remove and replace the patch, whether a patch may be cut). Always verify the patient's understanding of the information. See ***Analysis of transdermal medication patch errors uncovers a "patchwork" of safety challenges*** in the March 2021 issue of this newsletter for more recommendations to prevent errors with transdermal patches.

Prescribing and dispensing error with oral solution

A patient was prescribed gabapentin 100 mg by mouth three times daily as needed for pain. Instead of ordering gabapentin 100 mg oral capsules, the prescriber requested the pharmacy dispense a gabapentin oral solution. However, they ordered gabapentin 25 mg/mL oral solution, which is not commercially available, with the instructions for the patient to take 4 mL by mouth three times daily. When the prescription was entered into the pharmacy computer system, gabapentin 250 mg/5 mL (50 mg/mL) was selected, as that was the only concentration available in the pharmacy computer system, with the same instructions to take 4 mL by mouth three times daily as needed for pain. The prescription was dispensed twice with the incorrect instructions resulting in the patient taking 200 mg three times daily instead of 100 mg three times daily. When the pharmacy discovered the error, the patient was contacted and instructed to take 2 mL (or 100 mg) by mouth three times daily as needed for pain. The provider was also informed of the error. In addition to the fact that only the 250 mg/5 mL concentration was available, the pharmacy identified that the overlapping numbers in 250 mg and 25 mg may have contributed to the data entry error not being intercepted.

Ensure the drug information content stored in the electronic health record (EHR) systems is up to date. Configured EHRs to list the concentration of the commercially available product. On prescriptions, prescribers should express single-entity medication doses in metric weight (e.g., mg, mEq, mcg, units), not the volume alone (e.g., mL), even if an oral solution is available in a single strength. Including a metric weight dose improves safety because the volume could differ depending on the concentration of the medication. Labels on prescription oral liquids should specify the dose in mL only, and not both mg dose and mL, since patients may be confused by the two numbers in the instructions. The product's concentration should be listed elsewhere on the label. Pharmacies should provide patients with an appropriately sized metric-only oral dosing device (e.g., oral syringe, ENFit syringe) for safe dose measurement and administration of oral liquids. Pharmacists should also teach patients how to measure each dose by employing the teach-back method, which incorporates a return demonstration by the patient to confirm their ability to measure the correct dose.

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label with the patient, confirm the indication, and ensure it is the medication they expect.

Look-alike enalapril and escitalopram bottles! Two pharmacies submitted reports indicating the container labels for enalapril 20 mg tablets, an antihypertensive agent, and escitalopram 20 mg tablets, an antidepressant, both manufactured by Solco Healthcare, are nearly identical (**Figure 1**). Both products have similar looking names and use the same colors and design elements on the primary display panels. These products may also be stored near one another as they both start with the letter "E." To prevent mix-ups, explore ordering one product of the pair from a different manufacturer. Consider using shelf dividers to keep stock separated. If you relocate one of these products, post signage to direct pharmacy staff to the product's new location. Utilize barcode scanning during the dispensing process to help identify if the wrong product is selected from the shelf.

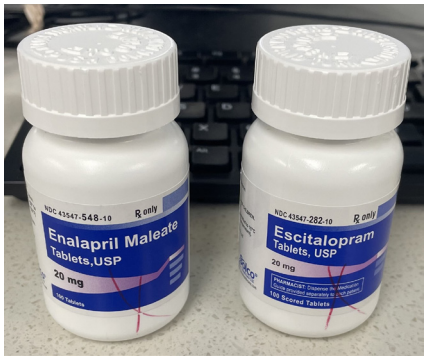

Figure 1. Bottles of enalapril 20 mg tablets (left) and escitalopram 20 mg tablets (right) by Solco Healthcare look nearly identical.

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