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ISMP An ECRI Affiliate

# Community/Ambulatory Care ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

## Wrong directions–mL instead of mg–provided on the prescription label of pediatric propranolol oral liquid

**PROBLEM:** Oral propranolol liquid was prescribed for a 7.2 kg 3-month-old baby with infantile hemangioma, a rapidly growing benign vascular tumor (www.ismp.org/ext/893). Propranolol induces vasoconstriction which results in color change and softening of the hemangioma. It is also thought that propranolol helps limit the growth of the hemangioma cells. The pharmacy contacted the physician's office to clarify the order. When the patient's mother picked up the prescription, propranolol 20 mg/5 mL (4 mg/mL) was dispensed with the following instructions: "Administer 3.5 mL once on day 1, administer 3.5 mL twice daily for the next 6 days, then administer 7.5 mL twice daily for a maintenance dose." Based on the concentration dispensed, this would equate to 14 mg once on day 1 (1.9 mg/kg/day), 14 mg twice daily for the next 6 days (3.9 mg/kg/day), followed by 30 mg twice daily (8.3 mg/kg/day) for the maintenance dose. This maintenance dose is much higher than the typical daily oral maintenance dose (1 to 3 mg/kg/day) for infants and children for this indication.

At the pharmacy, the mother was neither counseled nor provided with an oral syringe to administer the medication to her infant. After the mother returned home, she called the pharmacist to question the dose. The pharmacist confirmed that the dose was higher than recommended for a 7.2 kg infant with infantile hemangioma. However, the pharmacist stated, "It should be fine if this is how the doctor wanted it." If the mother was still concerned about the dose, the pharmacist suggested calling the physician's office herself.

The mother followed up with the prescriber to express her concerns and to relay that the pharmacist assured her that the dosing instructions she received matched what was on the original prescription. The prescriber confirmed that the dosing directions provided on the pharmacy label by the pharmacy were incorrect. The prescriber told the mother that, when the pharmacist called for clarification, the dosing directions were mistakenly communicated to the pharmacist in mL, not mg. The intended instructions were "3.5 mg (0.88 mL) for the first day (0.49 mg/kg/day), 3.5 mg (0.88 mL) twice daily for the following 6 days (0.97 mg/kg/day), followed by 7.5 mg (1.88 mL) twice daily (2.1 mg/kg/day) for the maintenance dose." Fortunately, the infant's mother kept questioning the directions and the error was caught before the infant was given the medication.

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### ISMP DISRESPECTFUL BEHAVIOR IN YOUR WORKPLACE SURVEY

Please remember to participate in our short survey on disrespectful behavior in your workplace. ISMP is seeking your input about your experiences with disrespectful behavior in community and ambulatory care work settings (e.g., community pharmacies, specialty pharmacies, long-term care pharmacies, physician practices, outpatient clinics). We would also love to learn about how your pharmacy, practice site, or organization has been working towards a culture of respect and the strategies that have worked. We strongly encourage pharmacists, pharmacy technicians, clerks, physicians, nurses, and other community and ambulatory care healthcare professionals to participate in the survey at: www.ismp.org/ext/879. Responses must be submitted by **May 27, 2022**.

## SAFETY briefs

HIGH-ALERT

**Bar code scan to prevent errors with look-alike packaging.** A patient was supposed to receive lamoTRIgine extended-release 200 mg tablets. However, she received a mix of manufacturer bottles of lamoTRIgine extended-release 200 mg tablets and lamoTRIgine extended-release 300 mg tablets. She discovered the error when she opened a bottle of lamoTRIgine extended-release 300 mg tablets and noticed they looked different than what she normally received. At first, she thought they may have been 200 mg tablets from a different generic manufacturer but after reviewing the container label she found out that they were 300 mg tablets.

**Figure 1.** The dosage strength on these bottles of lamoTRIgine extended-release tablets is printed to the right of the drug name, partially around the curve of the bottle, making the dosage strength more easily missed.

It is easy to see how these bottles could be confused despite the different shading used on the bottom of the labels and around the drug strength (**Figure 1**). The drug name and other information on the principal display panels are formatted similarly. Also, the drug strength is printed to the right of the drug name, around the curve of the bottle. This increases the risk that the strength may be missed when looking at multiple bottles at the same time.

To help prevent errors with look-alike packaging, the pharmacy should employ processes and technology that can intercept product selection errors. Pharmacies should utilize barcode scanning during production and scan each bottle used to fill a prescription, including each manu-

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Provided to members courtesy of vizient.

> Propranolol oral liquid — continued from page 1

**SAFE PRACTICE RECOMMENDATIONS:** There are three propranolol oral liquid concentrations available, including two concentrations of generic products, 20 mg/5 mL (4 mg/mL) and 40 mg/5 mL (8 mg/mL), and a different concentration for a brand product, **HEMANGEOL**, 4.28 mg/mL. To avoid confusion among the multiple concentrations, and also between mg and mL doses, propranolol oral liquid doses should always be prescribed in mg. Prescribers should include the patient's weight in metric units on the prescription. Otherwise, pharmacists will need to confirm the weight so they can calculate and verify the mg/kg dose. If the dose is outside of the normal range, pharmacists should clarify the order directly with the prescriber, referring to the mg dose. Once the drug has been prescribed in mg, pharmacists may need to calculate and transcribe the mL dose based on the drug's concentration for the patient's instructions if the electronic prescribing system does not calculate the volume automatically. Then, if the volume amount must be entered manually, an independent double check of the calculation should be required.

Labels on prescription oral liquids should specify the dose in mL in the instructions for use for the patient/parent to measure each dose, and then the product's concentration should be listed elsewhere on the label. Weight-based medication doses should be rounded and/or standardized automatically at the time of prescribing to a dose that is not greater than or less than 10% of the originally prescribed dose. For example, 3.5 mg (0.88 mL) of propranolol 4 mg/mL should be rounded to 3.6 mg (0.9 mL) to facilitate the ease of measuring doses. Pharmacies should provide patients with an appropriately sized metric-only oral syringe or dosing cup for safe dose measurement and administration of oral liquids. Pharmacists should also teach patients/parents how to measure each dose by employing the "teach-back" method using the dosing device, which incorporates a return demonstration by the patient/parent to confirm their ability. Importantly, when patients/parents express a safety concern, stop, listen, and investigate to confirm that there are not any errors (review our article, *Excuse me, I think there is an error with my prescription: Practitioners should respond with empathy and honesty* at: www.ismp.org/node/23867).

Incidentally, Hemangeol is the only liquid propranolol approved by the US Food and Drug Administration (FDA) for the treatment of proliferating infantile hemangioma requiring systemic therapy. The generic products are used off-label for this indication. In the US, the existing generic propranolol solutions are expressed in terms of propranolol hydrochloride, and FDA had previously requested that Hemangeol dosages and concentration be communicated similarly. Outside the US, the Hemangeol concentration is expressed as 3.75 mg/mL of propranolol base, which is equivalent to 4.28 mg/mL. Unfortunately, the Hemangeol 4.28 mg/mL concentration can add to the risk of dosage calculation errors when compared to the available generic 4 mg/mL or 8 mg/mL concentrations.

## Pharmacies should support and help patients navigate the path to access out-of-stock medications

A patient was prescribed **XATMEP** (methotrexate) oral solution to treat leukemia. The patient was receiving the medication via delivery from a specialty pharmacy. When a refill was requested, the technician working in the specialty pharmacy's call center processed the request and set up a delivery. After a pharmacist verified the entered order, it was then routed to a staff member working in the fulfillment area, a separate part of the pharmacy where the medications are stored, to fill the order. However, the pharmacy did not have the drug in stock and discovered it was on backorder and thus unavailable. The fulfillment staff person sent the prescription back to the call center technician and notified them the drug was not in stock and was on backorder so the pharmacy would not be able to fill it. The technician called the patient's mother to say that due to supply issues they could not provide the refill and

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facturer bottle that may be dispensed to a patient. Also, each dispensed bottle should have a pharmacy label affixed. As seen above, this was not done in this case. At the point-of-sale, open the bag and have the patient check what has been dispensed to make sure it is correct.

**Hidden pork content in Colace capsules.** Did you know that some **COLACE** (docusate sodium) capsules have ingredients sourced from pigs in their gelatin capsule? We didn't either until a nurse reported to us that a Muslim patient had recently ingested multiple doses. Unfortunately, the container and product labeling do not specify the pork content. People with food allergies or intolerances, or who want to avoid animal products for religious, cultural, or dietary reasons need to know the origin of the ingredients contained within their medication. We contacted Avrio Health who manufactures the brand product Colace (there are several generic formulations as well). Avrio Health confirmed that the gelatin used in the Colace capsules is made from pigskin and that the label and package insert do not specify that this is the source of the ingredients. It appears that under current regulations, the label is not required to detail the animal source of the gelatin. Alert colleagues and patients to this situation. If practitioners or patients have concerns about the inactive ingredients contained in a medication, they should contact the manufacturer for more information.

**Similar names of oral contraceptives.** An outpatient pharmacy received a hard-copy, typed prescription for the oral contraceptive **SYEDA** (drospirenone and ethinyl estradiol). However, the pharmacy technician accidentally selected a different oral contraceptive, **SLYND** (drospirenone), when entering the prescription into the pharmacy computer system. The verifying pharmacist did not catch the error and Slynd was dispensed to the patient.

After the patient picked up the prescription, she noticed that the packaging looked different from what she had received previously at another pharmacy. She returned to the dispensing pharmacy wondering if she had received the correct medication.

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that the pharmacy was not sure when they would be able to fill it. The technician did not give any resolution options to the mother, nor was a pharmacist notified.

The patient's mother called the prescriber to ask for options. The prescriber called another pharmacy and found that they had enough supply for two doses. The prescriber called the original pharmacy to express concern that no one had contacted them regarding the backorder and that the pharmacy did not help coordinate a plan of action for the patient to obtain the medication. It was noted that the pharmacy did have a protocol in place to alert the patient AND prescriber within a specified timeframe if they are unable to fill a prescription. It is unclear why the process broke down in this case.

Community and specialty pharmacy staff have been overwhelmed with drug shortages and backorders that have intensified during the coronavirus disease 2019 (COVID-19) pandemic. To prepare for these situations, establish procedures, which should include alerting pharmacists, on how to handle drug and supply shortages and educate staff on the procedures. Consider creating a checklist to help staff navigate and communicate issues when medications are unavailable. Periodically observe or check in with staff to see how the designed procedures are working. Develop electronic communication tools to alert practitioners to critical changes in a prescription's status as well as the reason for the change. Pharmacists should communicate with the prescriber and patient to find the best way for the patient to access the medication. This may include using a different strength or dosage form, obtaining the medication from a different pharmacy, or recommending alternative therapies when clinically appropriate.

## New ECRI and ISMP Headquarters

On April 19, 2022, ECRI and ISMP celebrated the opening of a new state-of-the-art global headquarters and medical device evaluation laboratory on a 24-acre campus near Philadelphia, PA. In 2020, ISMP became an affiliate of ECRI and together created the largest healthcare quality and safety entity in the world, driving greater value to healthcare across all care settings, including community, specialty, and hospital pharmacies. The opening of the new building marks an historic opportunity for the nation's largest patient safety organization to fulfill its mission and to usher in a new era of healthcare advancement and patient safety innovation.

With the opening of the new headquarters, ISMP's old office has closed. Our new address is 5200 Butler Pike, Plymouth Meeting, PA 19462. However, our telephone number remains the same: 215-947-7797. Of course, you can always reach us by email (ismpinfo@ismp.org) and via the Contact Us page (www.ismp.org/contact) on our website.


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The pharmacy investigated the situation and confirmed that the wrong product had been dispensed. Thankfully, the patient did not take any of the incorrect medication.

During their investigation, the pharmacy identified several contributing factors. Syeda was not normally stocked by the pharmacy, and thus staff were unfamiliar with it. Also, they found that the drug was not listed in their pharmacy software database. They determined that the look-alike similarity of the names—both have five characters, both start with "S," and both contain a "Y" and a D"—contributed to confirmation bias when the technician entered the drug into the pharmacy computer system. Finally, both medications share the same indication, and both contain drospirenone. Please alert your colleagues to this look-alike name pair. We have notified the US Food and Drug Administration about this name pair.

## Special Announcement

**Virtual MSI workshops**

Don't miss the opportunity to register for one of our unique 2-day, virtual ***ISMP Medication Safety Intensive (MSI)*** workshops being offered in 2022. Our next workshop is scheduled for **June 9 & 10, 2022**. For more dates in 2022 and to register, visit: www.ismp.org/node/127.

**To subscribe: www.ismp.org/node/126**

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