

EDUCATIONAL OBJECTIVES

After completing the continuing education activity, pharmacists and pharmacy technicians will be able to

- Describe the significance of the availability of each recently released over-the-counter medication or device
- List the common uses or indications for each over-the-counter medication or device
- Explain the directions for use for each over-the-counter medication or device



The University of Connecticut School of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Pharmacists and pharmacy technicians are eligible to participate in this application-based activity and will receive up to 0.1 CEU (1 contact hours) for completing the activity, passing the post-test with a grade of 70% or better, and completing an online evaluation. Statements of credit are available via the CPE Monitor online system and your participation will be recorded with CPE Monitor within 72 hours of submission

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You Asked for It! CE



Over-the-Counter (OTC) Medications and Devices Released within the Last Three Years

TARGET AUDIENCE: Pharmacists and pharmacy technicians interested in over-the-counter medication selection and counseling.

ABSTRACT: Demands on pharmacists have continued to increase over the past few years. Pharmacists feel confident about dispensing medications, but some do not feel equally as confident when recommending over-the-counter medications. It is important for pharmacists to stay informed about new over-the-counter medications and be able to counsel patients on the selection and use of these products. New over-the-counter medications released in the past few years include birth control, devices that detect heart arrhythmias, allergy remedies, and products to treat opioid overdoses.

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FACULTY DISCLOSURE: Dr. McFalls has no financial relationships with an ineligible company.

DISCLOSURE OF DISCUSSIONS of OFF-LABEL and INVESTIGATIONAL DRUG USE: This activity may contain discussion of off label/unapproved use of drugs. The content and views presented in this educational program are those of the faculty and do not necessarily represent those of the University of Connecticut School of Pharmacy. Please refer to the official prescribing information for each product for discussion of approved indications, contraindications, and warnings.

INTRODUCTION

Self-care involves patients' ability to diagnose and treat their own illness without the help of a health care practitioner. Ninety-six percent of patients believe that over-the-counter (OTC) medications make it easy to care for these self-care conditions.¹ Patients save \$56.8 billion annually when they use OTC/nonprescription medications instead of prescription medications.² Pharmacists and pharmacy technicians are frequently consulted about different self-care conditions and the appropriate choice of OTC medications and devices.

PAUSE AND PONDER: Would you be able to recognize the symptoms of an overdose?

Naloxone Nasal Spray

The Center for Disease Control and Prevention (CDC) reported that there were 106,363 opioid-related deaths during a 12-month period ending in July 2023.³ The Food and Drug Administration (FDA) originally approved Naloxone to reverse an opioid overdose in 2015 as prescription only.⁴ It moved to OTC/nonprescription status in March 2023 through the FDA's Rx-to-OTC switch process.^{5,6} The manufacturer drove this change to nonprescription status by providing data showing that the drug is safe and effective and that consumers could understand how to use the product based on the proposed labeling.⁵

Naloxone (Narcan, Emergent BioSolutions) was the first OTC medication approved to reverse opioid overdose in community settings. Patients (who use prescription or illegal opioids), caregivers, family members, or friends can now purchase naloxone in community pharmacies, grocery stores, and online without a prescription.^{5,7} Based on Federal law, people of any age can purchase naloxone, but state laws may differ.⁷ **Table 1** (below) describes symptoms of an opioid overdose. The overdose can result from use of fentanyl, heroin, morphine, oxycodone, and other opioids. Naloxone works by blocking the opiate receptors in the brain so that the opiate cannot exert its effects. If it is not an overdose situation, patients will experience no effect.⁵

Naloxone nasal spray contains only one dose and is not reusable. It is available in a 4 mg dose. Observers or caregivers should administer naloxone as soon as possible when they suspect an overdose. The observer/caregiver should lay the patient down on his or her back with their neck supported and the head tilted back. The caregiver should remove the tab from the nasal spray. It does not need to be primed. Caregivers place their thumb on the bottom of the red plunger and the first and middle fingers around the nozzle. The caregiver then places the tip of the nasal spray inside the patient's nose. They should press the red plunger to administer the medication. They can give additional doses every two to three minutes if needed. They should also call emergency services immediately.

Table 1. Opioid Overdose Symptoms⁵

- Body aches
- Diarrhea
- Fever
- Goose bumps
- Increased blood pressure
- Increased heart rate
- Nausea or vomiting
- Restlessness or irritability
- Sweating

During an overdose situation, the patient could experience withdrawal effects such as nausea, vomiting, sweating, tremors, shivering, or irritability.⁸ The cost is approximately \$45 for two single doses.⁹

A Naloxone Nasal Spray Training Device is available for anyone who wants to learn how to administer the nasal spray. The kit contains instructions and two training devices. It does not contain active medication.¹⁰

In July 2023, the FDA approved a second OTC naloxone product. RiVive (Harm Reduction Therapeutics) contains 3 mg naloxone. This is also a Rx-to-OTC change supported by evidence demonstrating that the naloxone levels that reach the blood stream are similar in the prescription and nonprescription product.¹¹ The approximate cost is \$36 for a twin pack.

PAUSE AND PONDER: How would you respond if a 13-year-old girl approached you and began asking questions about the norgestrel birth control? What questions would you ask?

Norgestrel 0.075 mg Tablets

In 2019, the CDC reported that 35.7% of pregnancies were unintended in women aged 15 to 44.¹² Unintended pregnancies may result in negative consequences due to a lack of early prenatal care and increased risk of preterm delivery.¹³ Having norgestrel available without a prescription may help to reduce unintended pregnancies.¹⁴

Opill (Perrigo) is the first nonprescription oral contraceptive. Opill tablets contain norgestrel 0.075 mg, which is a progestin, or a form of progesterone. It is only used to prevent pregnancy; it does not protect against sexually transmitted diseases such as HIV. The American College of Obstetricians and Gynecologists and the American Medical Association have endorsed this product. Women of any age can purchase Opill in community pharmacies, grocery stores, and online.^{14,15}

Norgestrel thickens the mucus in the cervix, preventing sperm from reaching the egg. The progestin may also inhibit ovulation, but not in all cases. Each pack contains 28 tablets, 24 active tablets that contain progestin and four inactive tablets that do not contain progestin. Norgestrel will begin working two days after the patient starts a pack and patients must take one tablet at the same time daily to be effective.

Missing tablets or not taking the tablets at the same time every day may reduce the birth control's effectiveness and increase the chance of pregnancy. If a patient fails to take the tablet by three hours or more of her scheduled time, she should take the next tablet as soon as possible. In this case, she and her partner should also use condoms (or another backup method of birth control) or avoid sex (vaginal) for the next two days.¹⁵ Once a pack is completed, patients should start the next pack without

Table 2. Questions Pharmacists Should Ask Patient about OTC Hearing Aids²⁰

- Are you 18 years or older?
- Why do you think you need a hearing aid?
- Have you had your hearing tested either by a professional or by using an online tool?
- Do sounds appear muffled?
- Do you have trouble hearing in a group or a noisy area?
- Do you turn the television up to an excessively high level?

any break in between.¹⁶ With typical use, the pregnancy rate is 9 in 100 during the first year of progestin-only tablets and for perfect use (never forgetting to take a tablet and taking the same time every day), the pregnancy rate is 1 in 100 women.¹⁵

Patients may experience side effects such as headache, dizziness, nausea, fatigue, cramps, or bloating.¹⁶ Progestin-only medications are contraindicated in women who have a history of lupus or breast cancer. Opill will be available on store shelves in March 2024. The suggested cost is \$19.99 for a one month supply.¹⁷

OTC Hearing Aids

Approximately 30 million adults in the United States have some type of hearing loss.¹⁸ OTC hearing aids are credited for improving the quality of life in patients, according to a study in the *Journal of the American Medical Association*.¹⁹ The study used a previously validated model (Decision model of the Burden of Hearing Loss Across the Lifespan: DeciBHAL-US) and simulated the projected probability of hearing loss and the use of traditional and OTC hearing aids in 40- and 50-year old males and females. Use of OTC hearing aids resulted in a \$70 to \$200 savings over a lifetime. Patients also began using OTC hearing aids earlier in life compared to traditional hearing aids (77.6 versus 78.9 years respectively).¹⁹ The OTC Hearing Aid Act provided the opportunity for patients to purchase OTC hearing aid devices without a medical examination or the necessity of being fitted by a hearing aid specialist.

OTC hearing aids are approved for adults 18 years of age and older and can be purchased online or in stores.¹⁸ OTC hearing aids are appropriate for patients with mild or moderate hearing loss. They are not appropriate for severe or profound hearing loss. OTC hearing devices have limits on the maximum output and would not treat severe hearing loss appropriately. **Table 2** (above) provides questions that a pharmacist might ask a patient regarding use of OTC hearing aids.

Patients wear OTC hearing aids behind or in the ear canal; implantation is not required. Sound is amplified in the ear canal and moved to the inner ear, where processing and transmission to the brain occurs.¹⁸

Patients should first test their hearing by using an online resource that is provided on the product's website. Once the re-

sults are provided, patients can select the best product for their needs using online product selection tools, based on their brand name choice. **Table 3** (below) lists features of some OTC hearing devices.²¹

Brands include Jabra Enhance, Audicus, and MDHearing. Costs range from \$200 to \$1000 per pair.²² Some health insurance companies may provide coverage for OTC hearing devices based on specific brands.²³

Lidocaine 4% Patch

Lidocaine is a topical anesthetic and works by inhibiting nerve impulse conduction. It provides a numbing sensation and is used to treat minor pain. Areas that can be treated include the back, neck, shoulders, and knees/elbows.²⁴ Lidocaine patches are not appropriate for areas of inflammation.²⁵

Lidocaine patches can be used on patients 12 years of age and older. Patients apply the patch to the affected area of the skin every six to eight hours and should not exceed three applications per day.¹ The patch may fall off if exposed to water, so waiting until the patch is off is the best time to shower or swim. Patches should not be applied to damaged or broken skin. The patch should not be covered with a bandage or a heating pad because too much lidocaine may be absorbed through the skin.²⁵

After the patch is removed, it can be discarded in the trash after it's folded in half (adhesive side in).²⁵ Common side effects include warmth or stinging.²⁶ This product should not be used longer than seven days.

Brand names include Salonpas (lidocaine 4%) Pain Relieving Gel Patch (approximate cost is \$11 for 6 patches) and Aspercreme (lidocaine 4%) Lidocaine Pain Relief Patch (approximate cost is \$10 for 3 patches).²⁴ Pharmacists and technicians should pay careful attention to brand name products with different ingredi-

Table 3. Features of some OTC Hearing Devices²¹

- Advanced acoustics
- Bluetooth streaming
- Hands-free phone calling
- Rechargeable
- Water resistant

ents. Salonpas Pain Relieving Patch contains camphor, methyl salicylate, and menthol.

Diclofenac Sodium 1% Gel

Diclofenac topical gel was also changed to nonprescription through the Rx-to-OTC switch process. The FDA approved it as a prescription in 2007 and approved the move to nonprescription status in 2020.²⁷

Voltaren (Haleon) is a nonsteroidal anti-inflammatory (NSAID) gel, which means that it reduces prostaglandins, which are often responsible for inflammation. It is approved for the treatment of arthritis pain in the hand, wrist, elbow, foot, ankle, or knee in adults older than 18 years. It is not approved for sprains, strains, or sport injuries.²⁷

Diclofenac relieves joint pain and stiffness.¹ Dosing is based on the area of application. Patients apply 2.25 inches to the upper body (hand, wrist, elbow) and apply 4.5 inches to the lower body (foot, ankle, knee). The dose is measured using an enclosed dosing card.

Diclofenac comes with an easy twist cap, which is helpful for patients with arthritis. The gel should be rubbed into the affected area up to four times a day for up to 21 days.²⁸ Voltaren does not feel greasy and has a clean scent, compared to other topical preparations used to treat joint pain and stiffness. Common side effects include mild skin irritation. Patients who are allergic to aspirin should not use diclofenac topical gel.²⁷ Diclofenac has limited systemic absorption and provides pain relief at the site of application.²⁹ Diclofenac topical gel does not work immediately. Patients may not notice relief for one week.²⁷

The cost is approximately \$19 for a 3.5 oz tube.³⁰

PAUSE AND PONDER: What symptoms would patients experience if they thought they have atrial fibrillation?

KardiaMobile

KardiaMobile (Alivecor) is used as a personal electrocardiogram (ECG), which measures the electrical activity in the heart. It is FDA-cleared. KardiaMobile is a single-lead ECG used to detect common arrhythmias such as atrial fibrillation, bradycardia, and tachycardia in 30 seconds.³¹ More than 454,000 hospitalizations occur each year in the United States due to atrial fibrillation.³²

The KardiaMobile device is the size of a credit card and pairs or communicates with a smartphone. Patients open the Kardia app on their smartphone and press “Record now.” The patient should place the KardiaMobile device near the smartphone so that the two can connect. The patient places two fingers on each of the pads on the KardiaMobile device. After a few seconds, the results appear in the Kardia app. Patients can save the results or email them to a health care practitioner.³¹ Patients also have access for



one year to KardiaCare, which is a service that includes ECG evaluations by cardiologists and monthly reports.³³

The sensitivity and specificity for atrial fibrillation are 92% and 95%, respectively, and 85% and 83% for normal sinus rhythm.³⁴

The Apple Watch also provides a similar service for the detection of heart arrhythmias. According to a study conducted in 2022, the Apple Watch and KardiaMobile can both detect rhythm and heart rate issues but the KardiaMobile had a nonsignificant trend toward better accuracy and rhythm detection.³²

The approximate cost for the KardiaMobile device is \$79.³¹

Azelastine HCl 0.15% Nasal Spray

Azelastine (Astepro, Bayer) is approved for the temporary relief of nasal congestion, runny nose, and sneezing due to indoor and outdoor allergies. This is the first available OTC antihistamine nasal spray. It is steroid free and approved for adults and children 6 years of age and older.³⁵ About 25.7% of adults and 18.9% of children have seasonal allergies.³⁶

Azelastine is an H₁-receptor antagonist that prevents histamine from activating the histamine receptor and producing symptoms such as nasal congestion, runny nose, and sneezing. Patients should prime the spray before using it by pumping the spray until a fine mist comes out.³⁷ Before using the spray, they must blow their nose to clear the nostrils. Patients may then tilt the head downward and insert the tip ¼” to ½” into the nostril. Patients then press the pump once and sniff gently.³⁸

Children 6 to 11 years of age should use one spray in each nostril twice daily. Children 12 years of age and older and adults should use one or two sprays in each nostril once or twice daily. Common adverse effects include runny nose, headache, and bitter taste. If patients experience drowsiness, they can use the spray

at bedtime (and this is a good counseling point). The labeling recommends avoiding azelastine with alcohol or sedatives. Patients should experience relief within the first three hours of the dose.¹

If the nozzle is clogged, the patient should unscrew the spray pump unit. The patient should fill a bowl or container with warm water, soak the nozzle, and pump the nozzle several times under water to clear the clog. Finally, the patient should let the nozzle dry before putting it back on the bottle. The product will need to be primed again before the next use.³⁸

The cost is approximately \$24 for 120 metered sprays.³⁹

Olopatadine Hydrochloride 0.1%

Olopatadine (Pataday, Alcon) is used to treat itchy, red eyes caused by ragweed, grass, animal hair, and pollen allergies.⁴⁰ Forty percent of the population has experienced itchy, red eyes due to allergies.⁴¹ Olopatadine is a mast cell stabilizer, which prevents histamine from forming during the allergic cascade.²⁷ Patients 2 years of age and older can use this product. The dose is one drop in the affected eye twice daily every six to eight hours. Reminding patients to remove contacts before use and wait 10 minutes after using the drops before reinserting them is a key counseling point.⁴²

Patients should stop using the product if they experience changes in vision, increased eye redness, or eye pain.²⁷ The cost is approximately \$20 for a 5 mL bottle.⁴²

Pataday (olopatadine 0.2%) Once Daily Relief and Pataday (olopatadine 0.7%) Once Daily Relief Extra Strength are also available as nonprescription products.⁴³



Mometasone Furoate 50 mcg Nasal Spray

Mometasone furoate (Nasonex, Perrigo) is used to treat allergies, such as hay fever, that produces symptoms such as nasal congestion, runny and itchy nose, and sneezing.⁴⁴ Mometasone is a corticosteroid.⁴⁰ It blocks the release of substances that produce inflammation in the body. Nasonex can be used in patients 2 years of age and older. It is the first nonprescription nasal steroid and is full prescription strength.⁴⁰

As with many other nasal products, the steps for administration start with shaking mometasone furoate before each use and executing a priming spray before the first use. The patient should

- insert the tip of the bottle in the nostril using a finger to hold the other nostril closed
- breathe in and spray at the same time
- repeat the process in the other nostril
- avoid blowing their nose right after using the nasal spray.⁴⁴

Patients 2 to 11 years of age should use one spray in each nostril once daily and patients 2 years of age and older should use two sprays in each nostril once daily. Stinging of the nasal passages is a common side effect. The product must be discarded after 75 days from the first use, even if product remains in the bottle.⁴⁴ Pharmacists and pharmacy technicians can remind patients to note the day they start using the product and/or the day when it needs to be discarded on the label. The cost is approximately \$15 for 60 sprays.⁴⁵

Ivermectin 0.5% Lotion

Approximately 6 to 12 million cases of head lice occur each year. Children between the ages of 3 and 11 years are most commonly affected.⁴⁶ Ivermectin was originally available by prescription only. In 2020, the manufacturer started the process to change the classification to nonprescription. Ivermectin lotion is no longer available as a prescription.⁴⁷

Head lice are parasites that survive by feeding on human blood. Lice are spread by person-to-person contact in close environments. Adult head lice are between 2 to 3 mm in length and move by crawling; they cannot hop or fly.⁴⁶ Common symptoms of head lice include itching on the head and scratching behind the ears.⁴⁸

Ivermectin 0.5% lotion (Sklice, Azurity Pharmaceuticals) is used to treat head lice and nits and is approved for children 6 months of age and older. Sklice is applied to dry hair and the scalp. The entire scalp and the hair nearest the scalp should be completely covered before the person applying the lotion pulls it through to the end of the hair. Patients may require the entire tube of product. Sklice is left on the hair for 10 minutes and then rinsed with water only. Patients should wait 24 hours before applying shampoo. Side effects include ocular irritation and a feeling of burning skin. These effects are rare.

Lice eradication is possible with one treatment. Treatment is effective for 94.9% of patients.⁴⁹ The approximate cost is \$293 for 177 grams, which is a single treatment.⁵⁰ Generic alternatives are also available. Other therapies for head lice include permethrin (approximate cost is \$39)⁵¹ and pyrethrin/piperonyl butoxide (approximate cost is \$14)⁵².

CONCLUSION

More than 700 products have been changed to OTC status through the Rx-to-OTC switch process.⁵³ More are sure to come. It is very important that pharmacists and pharmacy technicians stay up-to-date with not only products on the market from the Rx-to-OTC switch process but also with entirely new product entities. Continuing education programs, product websites, and package information are an appropriate way to become familiar with all new product releases.

Figure 1. Safety and Counseling Related to New OTC Products

Best

- 1 **Be COMMUNITY CHAMPIONS** and whenever possible, educate your community about the FDA's Consumer Complaint site (<https://www.fda.gov/safety/report-problem-fda/consumer-complaint-coordinators>)
- 2 **Encourage discussion** with patients about OTC and prescription drugs use stressing that some products are similar but the dosing may be different
- 3 **Follow the news about new OTC medicines**, especially those that are making the jump from prescription to OTC! Prepare for new OTCs in advance

Better

- 1 **Post information about OTC on bulletin boards in patient waiting areas** using patient-friendly language
- 2 **Report adverse events related to any OTC product** through the United States Food and Drug Administration Adverse Event Reporting System (FAERS)
- 3 **Remind patients to read labels carefully** and counsel patients who take or administer OTC products to follow the directions

Good

- 1 **Be familiar with the OTCs you stock** and how they are organized
- 2 **Know which conditions are able to be treated with OTC** and which need professional intervention
- 3 **Understand that many people use OTC products** and may need reliable information

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