Objectives

- Understand the indications and side effects of common over-the-counter medications
- Know the characteristics of drugs used to treat cough/colds, allergies, constipation/diarrhea, and pain/fever
- Identify combination products that contain aspirin or acetaminophen
- Appreciate differences between OTC medications in the same drug class
OTC Drug Monograph Process

- Three-phased public rulemaking process
  - **Phase 1:** Advisory review panels
    - Medication safety and effectiveness
    - Appropriate labeling, including indications, instructions, and warnings about side effects
  - **Phase 2:** Agency’s review
    - Publish conclusions of review of ingredients, public comment, and new data in Federal Register in form of tentative final monograph (TFM)
  - **Phase 3:** Publication of final regulations
  - FDA Monograph system is difficult to change!

Overview of Drug Classes

- **Over-the-Counter (OTC)**
  - Patients may purchase and use directly

- **“Behind-the-Counter (BTC)”**
  - Not an official drug class
  - Pseudoephedrine

- **Prescription**
  - Requires order of a licensed individual practitioner for delivery to a patient
  - Can be a pharmacist with collaborative practice
Top Sellers in Adults

- Top Selling in 2013
  - Advil® - $491 million
  - Aleve® - $370 million
  - Prilosec - $359 million
  - Zyrtec® - $317 million
  - Bayer® - $222 million
  - Tylenol® - 200 million

Top Sellers in Pediatrics

- Top-Selling OTC Medications for Pediatrics:
  - Cough / Cold
  - Analgesics / Antipyretics
  - Allergy
  - Gastrointestinal
What Are Generic Drugs?

- **Compared to a brand named drug:**
  - Contain the same active ingredients
  - Must be identical in strength, dosage form, and route of administration
  - Have the same indications
  - Considered bioequivalent
  - Meet the same batch requirements for identity, strength, purity, and quality
  - Manufactured under the same FDA standards

*We save $8 to $10 billion a year at retail pharmacies alone*

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**Cough and Cold Products**
AAP Recommendations

“Research has shown these products offer little benefit to young children and can have potentially serious side effects. Many cough and cold products for children have more than one ingredient, increasing the chance of accidental overdose if combined with another product.”

Cough and Cold Meds for Kids

- Bottom Line: won’t make kids feel better any faster

- If decided safe to use meds, use only if...
  - ...single-ingredients for most bothersome symptoms
  - ...the meds make the child more comfortable
  - ...the meds aren’t causing bothersome side effects

- Helpful Resources:
  - healthychildren.org [AAP] – “Coughs and Colds: Medicines or Home Remedies?”
Nasal Congestion

• **Pseudoephedrine (Sudafed)**
  - How it works:
    - Constricts blood vessels in respiratory tract
    - Relaxes lungs, ↑ heart rate and contraction
  - Side effects:
    - Palpitations, increased diastolic blood pressure
    - Anxiety, insomnia, tremors, irritability, seizures

• **Phenylephrine (Sudafed PE)**
  - How it works:
    - Constricts blood vessels
  - Side effects:
    - Rebound nasal congestion, high blood pressure, nervousness

Nasal Congestion

• **Oxymetazoline (Afrin, Neo-Synephrine Spray)**
  - How it works:
    - Constricts blood vessels in nasal passages
  - Side Effects:
    - Dryness of nasal mucosa, nasal irritation, sneezing
  - Caution:
    - Risk of severe rebound congestion if used > 3 days
Cough Suppressants

- **Dextromethorphan (Delsym, Robitussin - DM)**
  - How it works:
    - Depresses medullary cough center (like codeine)
  - Side effects:
    - Dizziness, fatigue, nausea/vomiting, confusion
  - Cautions:
    - Don’t use with excessive secretions or phlegm production
    - Use with certain antidepressants can lead to serotonin syndrome
    - Drug of abuse (euphoric effects) -- can lead to brain damage, seizures, loss of consciousness, and death

Expectorants

- **Guaifenesin (Robitussin, Mucinex)**
  - How it works:
    - Irritates stomach lining to stimulate respiratory tract secretions (more volume, less thickness)
  - Side effects:
    - Drowsiness, nausea/vomiting, headache
  - Special considerations:
    - Take with a full glass of water and stay hydrated
    - Labeled for kids 2+ years
Other Products

- Zinc
- Vitamin C
- Echinacea
- Cough Lozenges
- Vick’s VapoRub
- Antihistamines

Non-Pharmacologic Options for Kids

- Nasal Congestion:
  - Hydration, hydration, hydration (warm liquids)
  - Bulb suction and upright positioning
  - Topical saline or warm water (drops/spray/washes)

- Cough Suppressants:
  - 3 mo – 1 yr: warm/clear fluids (1-3 teaspoons) 4x/day
    - AVOID HONEY! (risk of infantile botulism)
  - 1+ yr: Honey (or corn syrup), ½-1 teaspoons as needed
    - Thins secretions, loosens cough
  - 6+ yr: Cough drops (or hard candy)
Antihistamines

- Products differ in how well they get into the brain and how specific they are for receptors
- Age limits vary on the product and indication
- **First generations = Sedating = Nonselective:**
  - Diphenhydramine (Benadryl)
  - Chlorpheniramine
- **Second generations = Non-sedating = Selective:**
  - Loratidine (Claritin)
  - Fexofenadine (Allegra)
  - Cetirizine (Zyrtec)
Antihistamines

- How they work:
  - Blocks histamine receptors in the gastrointestinal tract, blood vessels, and respiratory tract
- Side effects:
  - Drowsiness, dry mouth, urinary retention, blurry vision, headache, constipation, confusion
- Special considerations:
  - Elderly and pediatrics

Intranasal Steroids

- OTC Products:
  - Nasacort (triamicinolone)
  - Flonase (fluticasone propionate)
- Rx only:
  - Nasonex (mometasone)
  - Rhinocort Aqua (budesonide)
- How they work:
  - Constricts blood vessels in the nose and decreases inflammation in the nasal passages
- Side effects:
  - Headache, sore throat, bloody nose
Intranasal Steroids

- **The most effective single maintenance therapy for allergic rhinitis**
- Symptoms of allergic rhinitis:
  - Postnasal drip, sneezing, nasal discharge, nasal itch
- Maximal effect may require **several days or weeks** of use in patients with long-standing untreated symptoms of allergic rhinitis

Cromolyn Sodium (NasalCrom)

- How it works:
  - Stabilizes mast cells to prevent the release of histamine and other inflammatory chemicals
- Side effects:
  - Headache, bad taste, cough, local nasal reactions
- Notes:
  - Great when used in a patient who is anticipating contact with a specific allergen
  - No known drug interactions
  - Labeled for age 2+ years old for allergic rhinitis
Constipation and Diarrhea

Constipation

- An increasing problem due to sedentary lifestyle, inadequate water intake, and fiber-poor diets
- Opioid-induced constipation:
  - Narcotic medications decrease bowel movement, decrease intestinal secretions, and increase fluid absorption from the bowel
  - Prevention with lifestyle modifications and medications is critical
Constipation

• **Osmotic Laxatives**
  - How they work:
    - Helps retain water in the colon and promotes peristalsis
  - Side effects:
    - Diarrhea, bloating, cramping, flatulence, nausea
  - Products:
    - PEG 3350 (MiraLax, GoLytely)
    - Magnesium Hydroxide (Milk of Magnesia)
    - Glycerin (suppository or rectal solutions)

• **Lubricants/Stool Softeners**
  - How they work:
    - Reduce surface tension of the oil-water interface of the stool, increasing water and fat in stool
  - Side effects:
    - Oil seepage (anal leakage), diarrhea, abdominal cramping, depletion of fat-soluble vitamins
  - Products:
    - Docusate (Colace, DDS)
    - Mineral Oil
**Constipation**

- **Stimulant Laxatives**
  - How they work:
    - Increase peristalsis in the GI tract (stimulates nerves)
  - Side effects:
    - Diarrhea, cramping, nausea
  - Products:
    - Senna (Senokot, Ex-Lax)
    - Bisacodyl (Dulcolax, Bisco-Lax)
  - Special considerations:
    - Can be habit-forming—long term use can result in dependence and loss of normal bowel function

**Diarrhea**

- **Loperamide (Imodium AD)**
  - How it works:
    - Slows intestinal movement and prolongs stool transit time by acting on opioid receptors in intestinal muscles
  - Side effects:
    - Constipation, nausea, ileus
  - Notes:
    - Don’t use in children < 2 yrs of age with acute gastroenteritis
    - STOP use with abdominal distension or blood in stool
Diarrhea

- **Bismuth Subsalicylate (Pepto-Bismol)**
  - How it works:
    - Decreases secretions and inflammation, antimicrobial activity against bacteria and viral pathogens
  - Side effects:
    - Stool discoloration, bleeding, ulcers, tongue discoloration
  - Notes:
    - Don't use in age <12 years old
    - Salicylate = like aspirin
    - Drug interactions with blood thinners and NSAIDs

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Pain & Fever
Acetaminophen

- **How it works:**
  - Inhibits inflammatory chemicals in the brain, blocks peripheral pain impulses, and inhibits the heat-regulating center in the hypothalamus
- **Side effects:**
  - Nausea, itching, headache
- **Notes:**
  - Approved for use in infants and children

Prescription Acetaminophen Products

- **FDA statement effective January 14, 2014**
  - Combination products must limit the amount of acetaminophen to ≤ 325mg in each tab/capsule
  - Labels must now warn of the potential risk for **severe liver injury**
  - The risk of liver injury primarily occurs when patients take multiple products containing acetaminophen at one time and exceed the current **maximum dose of 4,000 milligrams within a 24-hour period**
Ibuprofen (Motrin, Advil)

- **How it works:**
  - Inhibits inflammatory substances produced by the body—decreases pain, fever, and inflammation
- **Side effects:**
  - Nausea, edema, rash, ringing of the ears, heartburn
- **Notes:**
  - Can cause ulcers in the stomach lining
  - Caution with anticoagulants, aspirin, and alcohol
  - Can make the kidneys not work as well
  - Approved in children > 6 months
  - Use LOWEST DOSE for SHORTEST TIME possible!
Naproxen (Aleve)

- **How it works:**
  - Inhibits inflammatory substances produced by the body—decreases pain, fever, and inflammation
- **Side effects:**
  - Edema, nausea, heartburn, itchy skin, dizziness
- **Notes:**
  - Can cause ulcers in the stomach lining
  - Can make the kidneys not work as well
  - Only approved for children ≥ 12 years old
  - Avoid in pregnancy (as well as ibuprofen)

Aspirin

- **How it works:**
  - Decrease inflammatory substances, inhibits platelets from sticking together—decrease fever, pain, inflammation
- **Side effects:**
  - Stomach ulcers, heartburn, ringing of the ears
- **Notes:**
  - Anticoagulation properties are phenomenal for patients with a history of heart attacks and strokes
  - Bleeding risks are real and patients should be aware
  - **NOT for use for pain/fever in age < 12**
  - **DO NOT use in kids with viral illness (Reye’s Syndrome)**
Some Drugs Are NOT for Children!

Final Remarks
Tips to OTC Products

- Read the medication labeling—look for:
  - Active ingredients
  - Warnings
  - Directions
- Use your resources:
  - Natural Medicines Comprehensive Database
  - MedlinePlus
- Don’t be afraid to ask for help!

Questions?
Resources