



Managing the Side Effects of PH Medications

2018 PHA on the Road – Long Beach, Calif.

Session Description

Dealing with PH symptoms can be emotionally and physically demanding. PH therapies are used to help alleviate the symptoms of the disease but can also cause side effects that you must learn to manage. Panelists will discuss common side effects for PH therapies and will provide strategies and tips for how to best manage them to maintain quality of life.

Learning Objectives

At the end of the session attendees will be able to:

- Understand and discuss the common side effects that PH medications can produce.
- Discuss strategies that can help alleviate and manage side effects of PH medications.
- Understand how your PH care team and you can communicate to discuss side effects to optimize your therapy and treatment plan.
- Discuss the prior authorization process for PH medications.

Common and Less Common PH Medication Side Effects

- Prostacyclin pathway medications (epoprostenol [Flolan[®], Veletri[®]], iloprost [Ventavis[®]], treprostinil [Orenitram[®], Remodulin[®], Tyvaso[®]], selexipag [Uptravi[®]]).
 - Headache
 - Diarrhea
 - Nausea
 - Flushing of the skin
 - Jaw pain
 - Pain in hands or feet
 - Low systemic blood pressure
- Endothelin receptor antagonists (ambrisentan [Letairis[®]], bosentan [Tracleer[®]], macitentan [Opsumit[®]]).
 - Nasal stuffiness or congestion
 - Flushing of the skin
 - Palpitations (rapid or skipped heart beats)
 - Swelling of legs or abdomen (fluid retention)
 - Elevated liver function tests
 - Anemia
 - Abdominal pain
 - Constipation
 - Bronchitis (irritation of the airways)
 - Urinary tract infection
 - Flu-like illness
 - Decreases in sperm count
- Phosphodiesterase Type 5 (PDE5) inhibitors (sildenafil [Revatio[®]], tadalafil [Adcirca[®]]).
 - Headache
 - Nasal congestion
 - Gastroesophageal reflux (known as GERD or heartburn)
 - Flushing of the skin
 - Nausea and diarrhea
 - Nose bleeds
 - Difficulty sleeping
 - Fluid retention
 - Muscle pain in the extremities (arm or leg)

- Soluble Guanylate Cyclase (sGC) stimulators (riociguat [Adempas®])
 - Headache
 - Nasal congestion
 - Gastroesophageal reflux (known as GERD or heartburn)
 - Low systemic blood pressure
 - Dizziness
 - Nausea and vomiting
 - Diarrhea or constipation
 - Anemia
 - Palpitations (rapid or skipped heart beats)
 - Nosebleeds
 - Edema (swelling in feet)

Managing Common PH Medication Side Effects

- When you begin a new PH medication:
 - Ask your PH care team about the likely side effects you may have.
 - Ask for suggestions to manage side effects without using additional medication.
 - Ask about medication (over the counter and/or prescription) that may help alleviate the side effects of your PH medications and the potential adverse effects of using these additional medications.
- While you are taking a PH medication:
 - Communicate with your provider about the adverse effects you experience.
 - There are many solutions that may allow you to continue taking the medication; do not stop the medication without approval and intervention from your doctor.
 - Ask for help from your specialty pharmacy and possibly from product-specific support programs and online or phone resources.

Risk Evaluation and Mitigation Strategy (REMS)

- A REMS is a drug safety and monitoring program that the Food and Drug Administration (FDA) can require for more than 70 individual medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.
 - **Current PAH medications subject to REMS monitoring programs include: Ambrisentan (Letairis®), Bosentan (Tracleer®), Macitentan (Opsumit®) and Riociguat (Adempas®)**
- REMS are designed to reinforce medication use behaviors and actions that support the safe use of that medication. While all medications have labeling that inform health care stakeholders about medication risks, only a few medications require a REMS.
- Patients play an essential role in REMS:
 - You may receive specific information or counseling about a serious risk associated with your medication, what actions you need to take to mitigate a serious risk and/or what symptoms you must watch for and/or report to your health care provider.
 - For some medications, you must sign a form acknowledging that you understand those risks before starting the medication; for other medications, you will be required to undergo lab testing.

Access to Medications

- Approach to the prior authorization process.
- What to expect when your provider orders a PH medication.
- Patient copay and/or deductible assistance programs.