



KRISTIN KELLER
EXECUTIVE VICE PRESIDENT

Kristin has spent the majority of her career providing strategic guidance to pharmaceutical clients on how to best leverage the interactive space. Prior to starting Compass in 2003, Kristin spent 5 years in account management at SimStar Internet Solutions (now Rosetta), working with clients such as Bristol-Myers Squibb, Novartis, Sanofi-Synthelabo, and Roche Pharmaceuticals.

Kristin initially became involved in this field because of a deep passion for healthcare and a love of medical science. It is this commitment to the improvement of healthcare education, access and outcomes that continues to fuel her today.

Kristin has a BA in Psychology with a minor in pre-medical studies from Mills College in Oakland, CA. She serves as Vice President of the board of Womanspace, a non-profit agency dedicated to serving victims of domestic violence and sexual assault. Kristin is also a passionate foodie and locavore, and when not working can be found in her kitchen or playing with her daughters.



healthcare communications

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C O M P S S

healthcare communications

**REMS:
FDA vs. Patient Reality**

April 9, 2010

REMS: What Is It?



The Food and Drug Administration Amendments Act of 2007 gave FDA the authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks.

Components of a REMS



Medication Guide/PPI

- Education tools provided to each patient when the drug is prescribed/dispensed

Communication Plan

- For example, letters to healthcare providers, communications to professional societies, professional education, etc.

Elements to Assure Safe Use

- Special requirements or restrictions to optimize safe use of products

Implementation System

- System to monitor, evaluate, and improve elements to assure safe use

Timetable for Assessment

- Minimum FDA requirement 18 months, 3 years, and 7 years after REMS approval (only compulsory element for all REMS programs)

REMS Types



Medication Guides are currently the predominant form of REMS

| REMS Types | Approx. Brands |
|-----------------------------|-----------------------|
| Medication Guide | 115 |
| Communication Plan | 30 |
| Elements To Assure Safe Use | 10 |
| Implementation System | 11 |

FDA States...



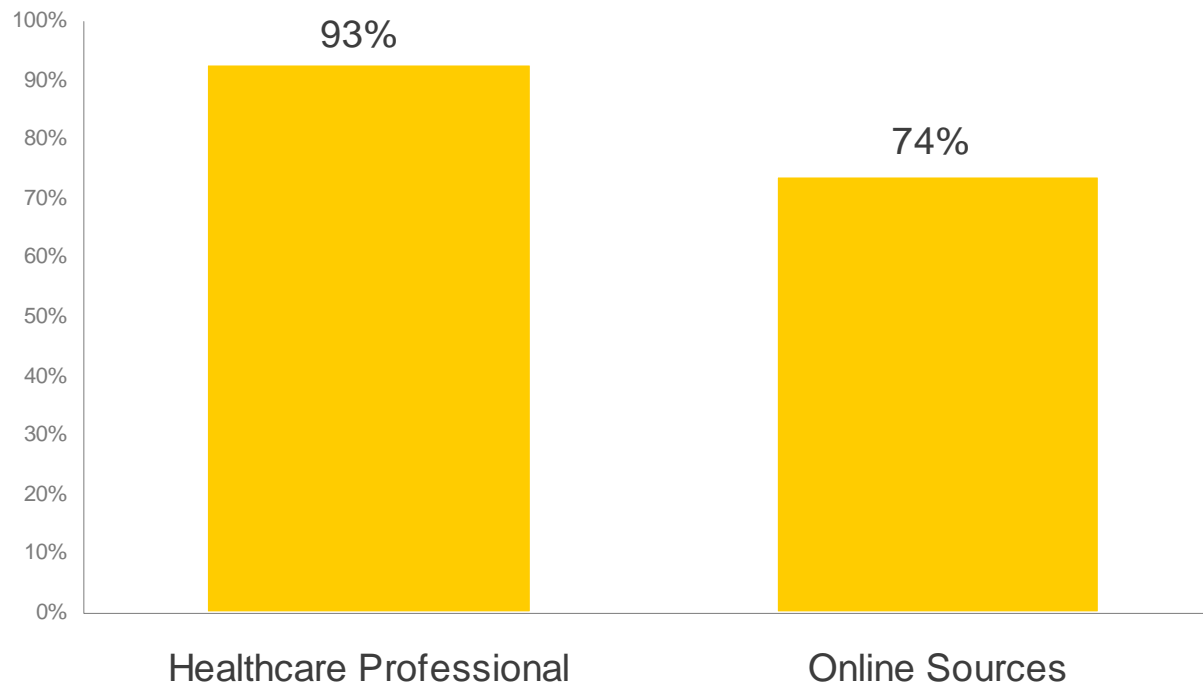
- “REMS goals should target the achievement of particular health outcomes or knowledge related to known safety risks and should be stated in a way that ***aims to achieve maximum risk reduction...***”

Guidance for Industry: Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications. September 2009; Drug Safety



Importance of Source of Health Information

Total Diagnosed and Treated / Used Source



Source: Patient Pathway Study, Google & comScore, April 2008 (n=HCP: 495; Online Source: 313)

...Not the labeling!

Source of Health Information

For OnTreatment Patients

| | |
|--|-----|
| Healthcare Professional | 69% |
| Internet | 44% |
| Drug label or accompanying information | 30% |
| Friends/Family | 21% |
| Brochures/pamphlets | 18% |

Source: Patient Pathway Study, Google & comScore, April 2008 (n=709)

The Big Picture



- No one touch point – even the physician – can optimally educate a patient and prepare them for therapy
 - Multi-channel approach is needed; medication guides are only a piece of the puzzle
- Neither physicians nor patients want the physician to be the only touch point throughout therapy
 - Primary information sources are the physician's office and the Internet
- Patient education sponsored by the brand is a responsibility *and* opportunity
 - Brands and FDA should be aligned on this...but aren't!


Letairis™
ambrisentan
5 mg and 10 mg Tablets

KEEP ME UPDATED

FULL PRESCRIBING INFORMATION

HOW TO GET LETAIRIS

RESOURCES

Once-Daily LETAIRIS
5 mg and 10 mg film-coated tablets

Please see the [full prescribing information](#) for complete details, including important safety information, including boxed WARNINGS on the possible risk of liver injury and the risk of serious birth defects.



INDICATION: LETAIRIS is an endothelin receptor antagonist (ERA) indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) in patients with WHO Class II or III symptoms to improve exercise capacity and delay clinical worsening.

Clinical worsening was defined as the first occurrence of death, lung transplantation, hospitalization for PAH, atrial septostomy, study withdrawal due to the addition of other PAH therapeutic agents, or study withdrawal due to early escape¹

Early escape criteria were two or more of the following after a minimum treatment period of 4 weeks: $\geq 20\%$ decrease in 6MWD; worsening WHO functional class; worsening right ventricular failure; rapidly progressing cardiac, hepatic, or renal failure; and refractory systolic hypotension < 85 mm Hg^{1,2}

[ABOUT RA](#)

[TREATING RA](#)

[ABOUT ACTEMRA](#)

[▶ HOW ACTEMRA IS DIFFERENT](#)

[▶ WHAT TO EXPECT](#)

[TOOLS AND RESOURCES](#)

[ACTEMRA PATIENT ASSISTANCE](#)

[MY PROFILE](#)

[SIGN UP](#)

[HEALTHCARE PROFESSIONALS](#)

What to Expect

During your infusion of ACTEMRA, you will sit in a chair or lie down on a cot or bed. A healthcare professional, usually a nurse, will give the intravenous (IV) infusion directly into a vein in your arm.

The infusion of ACTEMRA takes approximately one hour, so you may want to bring something to do to pass the time. You can read a book, listen to music, do a crossword puzzle, or just sit back and relax.

While it's normal to feel nervous at first about getting an IV infusion, many people see it as "time away" from a busy life. You may also find comfort in the fact that healthcare professionals are present to watch over the entire process and to answer any of your questions.

Your doctor or nurse can also explain more about adverse events that may occur during your infusion. Serious allergic reactions can happen with ACTEMRA. These reactions may not happen with your first infusion, and may happen with future infusions of ACTEMRA.

Tell your healthcare provider right away if you have any of the following signs of a serious allergic reaction:

- shortness of breath or trouble breathing
- skin rash
- swelling of the lips, tongue, or face
- chest pain
- feeling dizzy or faint

Remember, you are in the care of healthcare professionals who are experts at the infusion process. What's more, you are taking positive steps toward managing rheumatoid arthritis.

[Next: Tools and Resources](#)

This information does not take the place of talking to your healthcare provider about either your medical condition or your treatment with ACTEMRA. Talk with your healthcare provider if you have any questions about your treatment with ACTEMRA.

INDICATION

ACTEMRA is a prescription medicine called an interleukin-6 (IL-6) receptor inhibitor. ACTEMRA is used to treat adults with moderately to severely active rheumatoid arthritis (RA) after at least one other medicine called a tumor necrosis factor (TNF) antagonist has been used and did not work well.

RA PROFILER

The RA Profiler is an interactive resource that can help you talk to your rheumatologist.



SIGN UP FOR UPDATES

For the latest information about ACTEMRA, RA and site updates, [sign up now](#).



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- ▶ [About CHANTIX](#)
- ▶ [Important Safety Information](#)
- ▶ [How Your Doctor Can Help](#)
- ▶ [Getting Started with CHANTIX](#)

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▶ [How to Take CHANTIX](#)

▶ [Important CHANTIX Safety Information](#)

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Important CHANTIX Safety Information

Some people have had changes in behavior, hostility, agitation, depressed mood, suicidal thoughts or actions while using CHANTIX to help them quit smoking. Some people had these symptoms when they began taking CHANTIX, and others developed them after several weeks of treatment or after stopping CHANTIX. If you, your family, or caregiver notice agitation, hostility, depression, or changes in behavior, thinking, or mood that are not typical for you, or you develop suicidal thoughts or actions, anxiety, panic, aggression, anger, mania, abnormal sensations, hallucinations, paranoia, or confusion, stop taking CHANTIX and call your doctor right away. Also tell your doctor about any history of depression or other mental health problems before taking CHANTIX, as these symptoms may worsen while taking CHANTIX.

Some people can have serious skin reactions while taking CHANTIX, some of which can become life-threatening. These can include rash, swelling, redness, and peeling of the skin. Some people can have allergic reactions to CHANTIX, some of which can be life-threatening and include: swelling of the face, mouth, and throat that can cause trouble breathing. If you have these symptoms or have a rash with peeling skin or blisters in your mouth, stop taking CHANTIX and get medical attention right away.

In clinical trials, the most common side effects of CHANTIX include nausea (30%), sleep problems, constipation, gas, and/or vomiting. If you have side effects that bother you or don't go away, tell your doctor.

You may have trouble sleeping, vivid, unusual, or strange dreams while taking CHANTIX. Use caution driving or operating machinery until you know how CHANTIX may affect you.

What to tell your doctor before you begin taking CHANTIX.

Tell your doctor about all your medical conditions, including if you:

- Have kidney problems or get kidney dialysis. Your doctor may prescribe a lower dose of CHANTIX for you.
- Have experienced depression or other mental health problems, as they may worsen while taking CHANTIX.
- Have any allergies.
- Are pregnant or plan to become pregnant. CHANTIX has not been studied in pregnant women. It is not known if CHANTIX will harm your unborn baby. It is best to stop smoking

BYETTA Pen Tutorial

penintro - Mozilla Firefox

http://www.byetta.com/flash/penintro.html

New Pen Setup 10 mcg

BYETTA Pen Tutorial Step 5

Navigate using the menu below

- Step 1
- Step 2
- Step 3
- Step 4
- Step 5**
- Step 6

Pen Overview

5/6

STEP 5
With the needle pointing up and away from you, push the injection button in until it stops. Hold the injection button in and count slowly to 5.

AUDIO

Transferring data from www.byetta.com...

New to BYETTA?

Get off to an **Easy Start** by calling **1-800-868-1190** and speaking to a BYETTA specialist who will walk you through using the BYETTA Pen and taking your BYETTA medication.

Important Safety Information for BYETTA[®] (exenatide) injection

- Serious side effects can happen in people who take BYETTA, including inflammation of the pancreas (pancreatitis) which may be severe and lead to death. Before taking BYETTA, tell your healthcare provider if you have had pancreatitis, stones in your gallbladder (gallstones), a history of alcoholism, or high blood triglyceride levels. Call your healthcare provider right away if you have pain in your stomach area (abdomen) that is severe, and will not go away. The pain may happen with or without vomiting and may be felt going from your abdomen through to your back.
- Your risk for getting low blood sugar is higher if you take BYETTA with another medicine that can cause low blood sugar, such as a sulfonylurea. The dose of your sulfonylurea medicine may need to be lowered while you use BYETTA.
- BYETTA should not be used in people who have severe kidney problems and should be used

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Section 3

Now that you have done the one-time-only new pen setup, follow Section 3 for all of your injections.

ROUTINE USE

STEP 1 Check the Pen



- Wash hands prior to use.
- Check pen label to make sure it is your 5 mcg pen.
- Pull off the blue pen cap.



- Check BYETTA in the cartridge. The liquid should be clear, colorless, and free of particles. If it is not, do not use.

Note: A small air bubble will not harm you or affect your dose.

STEP 2 Attach the Needle



- Remove paper tab from outer needle shield.
- **Push** outer needle shield containing the needle **straight** onto pen, then **screw** needle on until secure.



- Pull off outer needle shield. **Do not** throw away.



- Pull off inner needle shield and throw away. A small drop of liquid may appear. This is normal.

STEP 3 Dial the Dose



- Check that the □ is in the dose window. If not, turn dose knob away from you (clockwise) **until it stops** and the □ is in the dose window.



- **Pull dose knob out until it stops** and the □ is in the dose window.



- Turn dose knob away from you **until it stops** at 5. Make sure that the 5 with the line under it is in the center of the dose window.

Note: If you cannot turn the dose knob away from you to the □, see **Commonly Asked Questions**, number 7, in Section 4 of this user manual.

STEP 4 Inject the Dose



- Grip pen firmly.
- Insert needle into skin using the under-the-skin (subcutaneous) injection



- **PUSH & HOLD** Use thumb to firmly push injection button in until it stops. Continue holding



- Injection is complete when the □ is in the center of the dose window.
- The pen is now ready to reset.

Section 4

COMMONLY ASKED QUESTIONS

1. Do I need to do the One-Time-Only New Pen Setup before every dose?

- No. The One-Time-Only New Pen Setup is done only once, just before each new pen is used for the first time.
- The purpose of the setup is to make sure that your BYETTA Pen is ready to use for the next 30 days.
- If you repeat the One-Time-Only New Pen Setup before each routine dose, you will not have enough BYETTA for 30 days. The small amount of BYETTA used in the new pen setup will not affect the 30-day supply of BYETTA.

2. Why are there air bubbles in the cartridge?

- A small air bubble is normal. It will not harm you or affect your dose.
- If the pen is stored with a needle attached, air bubbles may form in the cartridge. **Do not** store the pen with the needle attached.

3. What should I do if BYETTA does not come out of the needle tip after four tries during One-Time-Only New Pen Setup?

- Carefully put the outer needle shield back over the needle. Remove the needle by unscrewing it. Throw away the needle properly.
- Attach a new needle and repeat **One-Time-Only New Pen Setup, Steps B–E**, in Section 2 of this user manual. Once you see several drops or a stream of liquid coming out of the tip of the needle, the setup is complete.

4. Why do I see BYETTA leaking from my needle after I have finished my injection?

It is normal for a single drop to remain on the tip of your needle after your injection is complete. If you see more than one drop:

- You may not have received your full dose. **Do not inject another dose.** Talk with your healthcare provider about what to do about a partial dose.
- To make sure that you get your full dose, when you take your injections, **firmly push and hold** the injection button in and **slowly count to 5** (see Section 3, Step 4: Inject the Dose).

5. How can I tell when the injection is complete?

The injection is complete when:

- You have firmly pushed the injection button in all the way **until it stops** and
- You have **slowly counted to 5** while you are still holding the injection button in and the needle is still in your skin and
- The □ is in the center of the dose window.

If you hear a click sound from your BYETTA Pen, ignore it. You must follow all the steps listed above to make sure your injection is complete.

6. Where should I inject BYETTA?

Inject BYETTA into your abdomen, thigh, or upper arm using the injection method explained to you by your healthcare provider.



▶ [Injection Instructions and Video](#)

▶ [Getting Started Kit](#)

▶ [Talk to a Nurse](#)

▶ [HUMIRA Pen and Syringe Disposal](#)

▶ [Medication Reminders](#)

▶ [Tips from the myHUMIRA Panel](#)



Tips from myHUMIRA Panel Members

Get helpful, first-hand advice from our panel of experts and patients.

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Information You Should Know About HUMIRA[®] (adalimumab)

HUMIRA is a medicine called a tumor necrosis factor (TNF) blocker. **HUMIRA is taken by injection and is available by prescription only.**

HUMIRA is used to:

What Should a Brand Do?



- Consider a REMS as a mandate to engage your patients *more deeply*...not less
 - See the Med Guide as only a starting point
- Provide rich, meaningful educational experiences to set expectations, address safety concerns and encourage compliance
- Leverage your patient needs and information seeking as an opportunity for a relationship

What Should a Brand Do?

- Advocate to FDA to allow you to tie your REMS and education programs together
 - We need to focus on the big picture

