

Hospital Pharmacy 10/25–11/12

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Hospital Pharmacy 10/25-11/12

This time last year, we would not have dreamed that we would be holding our 2021 fall conference online—in fact, until two months ago, we were confident that we would be able to meet together in person and were preparing this Fall Hospital Pharmacy Conference to be held in Pittsburgh, PA. But the strain on hospitals from the Delta variant surge changed our plans, as it was not feasible for our Provider attendees to travel. So instead of gathering physically in Pittsburgh this fall, we will facilitate those connections between Providers and Suppliers in our online platform. We wish we could have welcomed you in-person in Pittsburgh, but we look forward to hosting you once again Live Online.

For the past 15 years, Health Connect Partners has been focused on our mission of bringing providers and suppliers together, and each of you have been a part of our journey. The lasting friendships and meaningful connections made at our events have forged us into a strong community. While we hate that it's been two years since we've held an in-person event, we are grateful to be able to provide each of you, our loyal providers and suppliers, an avenue to safely connect live online until we can all be back in the same physical location together.

We are delighted to host you for the next few weeks during our 2021 Fall Hospital Pharmacy Conference—Live Online! We realize that the need for connection in our healthcare communities has never been greater, even though we are not yet meeting in person. We look forward to bringing you this opportunity, which will allow you to connect face-to-face (live online), develop business relationships, be inspired by thought-provoking education, and discover new technologies and products.

If you have questions at any time during this event, stop by the help desk or call us at 615-449-6234. Our team is here for you and happy to help.

We are beyond grateful to all of you for your understanding and willingness to keep moving in a positive direction. We look forward to hosting you for this wonderful live online event.

David, Nelson and Jason



David Mason





Nelson Hendry



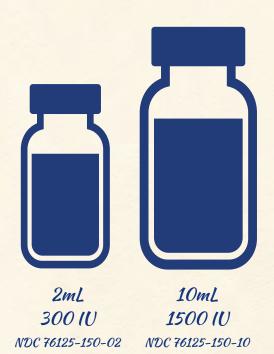


Jason Green





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connect with suppliers in a unique
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This new platform is designed to
give hospital providers
and supplier organizations the
ability to directly interact in a

In addition to providing the platform, Health Connect Partners is focused on driving high-quality traffic to each Virtual Supplier Showcase booth—just like we do during our in-person Supplier Showcase events. The Virtual Supplier Showcase is open for visits any time during the conference dates and is a required stop on the way to the educational sessions. Each provider executive will be encouraged to participate in a fun, interactive virtual experience allowing them to learn and request information along their journey through the Virtual Supplier Showcase.

Best of all—the Virtual Supplier Showcase platform allows provider executives to directly request information, and schedule meetings with suppliers through our live online meeting platform. Providers have a choice of requesting a meeting during the Live Online Reverse Expo or selecting a specific date and time for an on-demand meeting outside of the Live Online Reverse Expo times.



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the showcase area





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*All educational sessions will be available for on-demand viewing from 9:00am CT on Monday, October 25th until Friday, December 3rd.



educational session

KEYNOTE

Leading From Within: Driving Culture and Performance in a Post-Covid Era



Susan Reilly Salgado is a consultant, speaker, and thought leader whose expertise lies at the intersection of organizational culture and customer experience. Susan leverages 20+ years of academic and professional experience to help clients build remarkable teams who can deliver remarkable customer experiences.

Susan's work in this field began in the mid 1990s, when she was a regular guest of Danny Meyer's acclaimed restaurants in the Union Square Hospitality Group (USHG). Susan was inspired by the consistently exceptional customer experiences she had across Danny's many businesses, and set out to understand the secret of his success by studying the USHG restaurants for her doctoral dissertation. The result of her analysis was a model that explained the impact of effective leadership on organizational culture.

Upon completing her dissertation in 2003, Susan was invited to join USHG as its firstever Director of Culture and Learning. In this role, she created and implemented the company's leadership training programs, which were a fundamental component of the company's success in growing its culture throughout significant growth, including the creation and scaling of the Shake Shack brand. In 2010, she partnered with Danny Meyer to open a consultancy, Hospitality Quotient, and in 2017 founded her own firm, Grason Consulting, to provide consulting and training services.

Susan's consulting work and speaking engagements have allowed her to work with companies across more than 20 different industries, such as Delta Airlines. Hyatt Hotels, Goldman Sachs, Chanel, Cedars Sinai Hospital System, Chick-Fil-A, Sotheby's, Condé Nast, and Coca Cola. In addition to her PhD from NYU-Stern School of Business, Susan holds a BS and an MBA from Lehigh University and has been an invited speaker at numerous universities. Susan has been a contributor for Inc. Magazine, has recorded a TEDx talk, co-founded the NYC chapter of Conscious Capitalism, and was named one of Fast Company's 100 Most Creative People in Business.



learning objectives

After attending this presentation, attendees will learn to:

- Build stronger relationships at the directreport level to foster a greater connection to the team and the organization
- Continue evolving as an "employer of choice" despite the trials of coping with workforce challenges post-Covid
- Hold team members accountable to high standards of behavior and performance, while still making them feel you are their #1 advocate



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educational session

TWO

Live Q&A

Monday, November 1st 11:00am-11:15am CT



Preparing for Your Joint Commission Survey 2021 – Medication Management Focus

Jeannell Mansur, PharmD, RPh, CJCP, FASHP, FSMSO

Principal Consultant for Medication Management and Safety, Joint Commission Resources Jeannell Mansur is Principal Consultant for Medication Management and Safety for Joint Commission Resources and Joint Commission International. In this role, she provides direction to hospital leaders on medication safety design, medication system optimization and technology implementation to support patient safety and effectiveness. Her expertise in lean six sigma and change acceleration performance improvement methods and tools is of immense value to organizations that are seeking to implement effective and sustainable improvement to challenging issues. Also in her role as Principal Consultant, Dr. Mansur provides expertise to the Joint Commission enterprise on medication system themes. Dr. Mansur has been recognized for her distinguished work by the designation of Fellow with the American Society of Health

System Pharmacists and the American

Society for Medication Safety Officers.

She is a voting member of the United States Pharmacopeial (USP) Convention.

Dr. Mansur completed training with the Institute for Healthcare Improvement in medication safety under the direction of Drs. Donald Berwick and Lucian Leape. The learning from these leaders and the experiences from this Institute resulted in the crafting of a systems-based approach to medication safety that has molded Dr. Mansur's philosophies.

Dr. Mansur has extensive experience in all aspects of medication system design and implementation as well as hospital pharmacy which includes clinical, operational and management responsibilities. She was Director of Pharmaceutical Services for 12 years at the University of Chicago Medical Center before she became Executive Director for Pharmacy Informatics, where she was involved in the planning, building and implementation of the organization's electronic medical record.

learning objectives

After attending this presentation, attendees will be able to:

- Discuss top scored medication management standards and EPs and the status of surveys for 2021
- List four areas of survey focus relating to medication processes for 2021
- Describe new clarifications for insulin pumps
- Discuss top areas of focus for sterile compounding and status of surveying to USP 797 and USP 800





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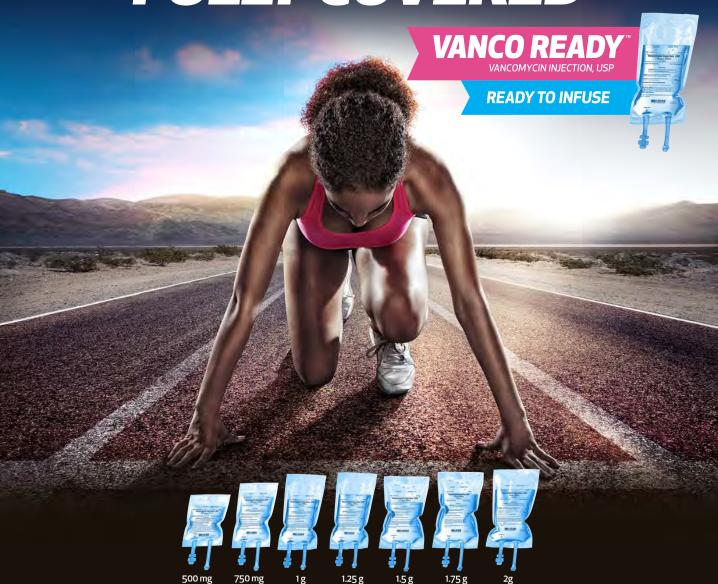


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educational session

Putting Advocacy into Action: A Policy Approach to White Bagging



Co-Speaker
Steven Lucio, Pharm.D., BCPS

Steven Lucio, PharmD, BCPS, leads the Vizient Center for Pharmacy Practice Excellence (CPPE) in providing Vizient members and the health care community with clinical and industry-related insights that support the Vizient mission to manage costs, improve quality of care and grow market performance. Steven and the CPPE team include trained pharmacists representing expertise in a wide range of clinical and operational pharmacy disciplines, including biosimilars, oncology, pediatrics, hazardous medications, drug supply, pharmacy operations, specialty pharmacy and regulatory compliance. From the expanding biosimilar markets to new gene therapies and other pipeline developments, Steven and this team apply their knowledge in maintaining a pulse on clinical, market and legislative developments, and forecast trends and potential impact to the Vizient community.

In addition, Steven is an industry leader and sought-after expert in the advancement and adoption of biosimilars as a key strategy in the management of drug price increases. As a leading authority, he has been featured in multiple publications

and broadcasts and is also the author of Biosimilars and Biologics: Implementation and Monitoring in a Healthcare Setting.

Steven is also a frequent contributor and presenter in support of Vizient's advocacy and public policy initiatives, highlighting the strategic and high-value role of pharmacy in the health care setting. He has provided insights on topics including essential medications, drug shortages, white-bagging, the Unapproved Drug Initiative and 340B strategies. In addition, he represents Vizient at legislative listening sessions, FDA briefings and other policy-making and stakeholder engagement opportunities.

Prior to joining Vizient, Steven practiced for almost 10 years within the Baylor Health Care System in various settings, including ICU clinical pharmacy and ambulatory care.

Steven holds a doctorate in pharmacy from Creighton University and a Bachelor of Science degree in pharmacy from the University of Texas at Austin, and is a board-certified pharmacotherapy specialist.



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Live Q&A

Tuesday, November 2nd 11:00am-11:15am CT

Co-Speaker

Wendy Gaudet, Pharm D., DPLA

Wendy Gaudet, Pharm D., DPLA, is currently Vice President of Operations at Our Lady of the Lake Regional Medical Center. She began her career as a Pharmacy Technician for a small retail pharmacy while earning her Bachelor of Science degree. Dr. Gaudet's first leadership position was serving as an Inpatient Pharmacy Manager and Pharmacist in Charge for a small hospital in Baton Rouge, Louisiana. She then advanced to Manager for Ambulatory Pharmacy Operations for Our Lady of the Lake. At OLOL, Dr. Gaudet continued to broaden her work in other departments and hospitals throughout the Franciscan Missionaries of Our Lady Health System, including serving a nine-month stint as Interim CEO and Vice President at Assumption Community Hospital, ultimately leading to her current Vice President role where she oversees all Pharmacy, Imaging, Lab, and Ortho Service Line operations throughout East Baton Rouge, Assumption, Livingston, and Ascension Parishes.

Dr. Gaudet earned her Bachelor of Science from the University of Arkansas at Monticello, and her Doctorate of Pharmacy from the University of Louisiana at Monroe, College of Pharmacy. She also completed her Lean Six Sigma Green Belt and Master Change Agent Certifications through GE certified programs, as well as her Diplomat of Pharmacy Leadership Academy through the American Society of Health System Pharmacists.

Dr. Gaudet is a member of ASHP and the Louisiana Society of Health System Pharmacists. She has served as a consultant for sterile cleanroom builds and for pharmacy work involving hazardous residue contamination, and she has spoken as Faculty for ASHPs Midyear presentation and for 340B Health engagements. She has received numerous awards and has been selected to represent OLOL in various community programs, including the 2020 Catholic Health Association Tomorrow's Leader Award, the 2018 Greater Baton Rouge Business Report Top 40 Under 40 Award, the 2017 Mother Gertrude Hennessy Leadership Award, The 2017 Proven Leader Program at OLOL, The Class of 2015 Baton Rouge Area Chamber Leadership Program, and the 2007 President's Award Recipient at the Baton Rouge General Hospital.



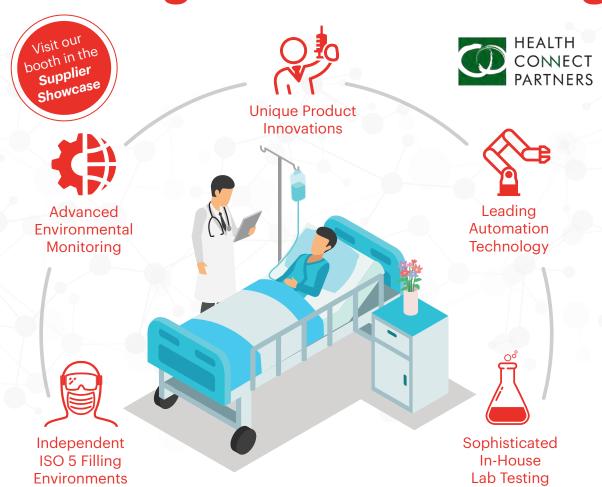
learning objectives

After attending this presentation, attendees will learn to:

- Define and differentiate between the strategies payers are implementing to affect medication acquisition and reimbursement
- Describe the potential for additional cost, waste, and patient care impact of these strategies like white bagging
- Identify a strategic plan to prepare and prevent additional expense and patient care disruption due to actions such as white bagging
- Explain how to participate in advocacy efforts to limit the negative impact of white bagging and/or other payer directed actions



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educational session FOUR

Live Q&A

Wednesday, November 3rd11:00am-11:15am CT

2021 Proposed USP Compounding Chapters— Sifting Through the Confusion: What's In, What's Out, What's Changed (now) and how FDA is Shaping the Conversation!



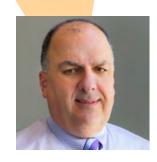
Lou Diorio, RPh, is a principal of LDT Health Solutions, Inc. (LDT), a medication safety and quality management consulting company, with over 70 years of combined pharmacy expertise serving clients internationally.

Lou is a graduate of Long Island University's Schwartz College of Pharmacy and is an adjunct Professor of Pharmacy Practice for the college and a preceptor of pharmacy students. He is also a member of the College's Alumni Executive Board.

Lou has extensive experience in IV and extemporaneous compounding. He lectures, writes, and consults on these topics, and lends his expertise to many State Boards of Pharmacy; and is a nationally recognized subject matter expert on compounding, robotics and automation. He has proctored the NYS Board of Pharmacy Licensure Exam (Part III) for Sterile Compounding. He has managed an FDA-registered cGMP manufacturing operation for Coram Healthcare (SoluNet™ LLC).

An active APhA member, Lou is a past Chair of APhA's APPM Academy of Practice and Management, an APhA Fellow, and was the Chair of APhA's Compounding Special Interest Group (SIG). He is also a current member of the Kappa Psi Pharmaceutical Fraternity Foundation Board of Directors, a member of the New York State Council of Health System Pharmacists Research and Education Committee, and a member of the New Jersey Society of Health System Pharmacists Industry Relations Committee.

Since 1985 Lou has practiced in many clinical settings, fulfilling many clinical and operational roles, including Chief Operating Officer of Hebrew Hospital Corporate Services, which is a multi-centered subacute and LTC hospital system in New York. He has also managed and practiced in home-care, hospital, and community settings.



learning objectives

After attending this presentation, attendees will be able to:

- Describe the genesis of USP Compounding Chapters, their scope, and the overlapping regulatory authorities who could enforce the USP standards
- Describe the current regulatory environment with focus on the most common citations confronting compounders who manipulate drug product for both 503A & 503B providers
- List three attributes (design elements) of a USP compliant compounding space for sterile or compounding
- Discuss the impact of the FDA's Insanitary Conditions guidance document on daily practice
- Outline three attributes of a quality compounder training program



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educational session

FIVE

Live Q&A

Thursday, November 4th 11:00am-11:15am CT



Connecting the Dots Between Leadership and Culture

Ernest R. Anderson, Jr. MS FASHP, FMSHP

Ernest R. Anderson, Jr formed his own consulting company in 2013. He consults in all aspects of pharmacy practice with Health System pharmacies, consulting with individual hospitals and multi-hospital systems. He is formerly System Vice President of Pharmacy at Steward Health Care, an 11-hospital system with corporate offices in Boston Massachusetts. Additionally, he spent 15 years as Director of Pharmacy at Lahey Clinic Medical Center in Burlington Massachusetts. Mr. Anderson is Associate Clinical Professor of Pharmacy at Northeastern University College of Pharmacy and Allied Health Professions, and Adjunct Associate Professor of Pharmacy at Massachusetts College of Pharmacy and Health Sciences in Boston.

Mr. Anderson received his Master's degree in hospital pharmacy from the Northeastern University College of Pharmacy and Allied Health Professions in Boston, Massachusetts in 1979 and his Bachelor's degree from Northeastern University College of Pharmacy and Allied Health Professions in 1976.

Mr. Anderson has given numerous presentations in his 45 years of pharmacy practice, both locally and nationally, on a variety of healthcare and leadership topics. He has published articles in journals such as Pharmacy Review, Hospital Pharmacy, Pharmacotherapy, Joint Commission Journal on Quality and Safety, Pharmacy Practice News and the American Journal of Health-System Pharmacy. Mr. Anderson served with ASHP as a delegate or alternate delegate from MSHP from 2001-2017. He has served ASHP as a member of the nominations committee for two years and as Chair and member of the Council for Public Policy for four years and Chair of the ASHP Fellow selection committee. He also serves on Development Committee for the ASHP Foundation. He is a past member of the Board of Trustees, Past Secretary and Past President of the Association of Community Cancer.

learning objectives

After attending this presentation, attendees will learn to:

- Differentiate a reactivity mindset from a creativity mindset
- Regulate their limbic system allowing full functionality of the pre-frontal cortex thus reducing stress
- Put the 4 in 4 Framework into action decreasing stress and improving creativity
- Identify the benefits of embedding effective values into the departmental culture
- Maximize creativity as a cultural departmental norm

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educational advisory board

Over the past year, our Educational Advisory Board has volunteered their valuable time to help us create an outstanding agenda. We greatly appreciate their dedication and want to recognize this esteemed group for all their hard work.

Simply put, without their time and expertise, this event would not have been possible.



Hospital Pharmacy Board Chair

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DAILY 8:00am-5:00pm CT

Session ONE
Monday
November 8

Session TWO
Tuesday
November 9

Session THREE
Wednesday
November 10

Session FOUR
Thursday
November 11

Session FIVE Friday
November 12













How to Prepare

- Schedule your Virtual System Test. If you have not done so already, contact
 us as soon as possible (615-449-6234) to schedule a meeting with our staff
 to ensure your system is ready for the Live Online! Reverse Expo.
- Chrome is the ideal browser for the Live Online! Reverse Expo platform.
- Disconnect VPN. Not doing so may prevent you from connecting to the Live Online! Reverse Expo platform.
- Check WiFi Speed. Streaming other devices during your virtual meetings may impact speed.
- Check Microphone & Video Capability. Use of headphones is suggested.
- Check your Virtual Meeting Space. Make sure you're satisfied with the lighting level, camera angle, and items that appear in the background when you're on camera.

Virtual Reverse Expo Day

- Early = On Time. Login to your Live Online! Reverse Expo dashboard
 15 minutes in advance of each meeting to prevent any lost meeting time due to technical issues.
- Focus on the Conversation. Contact information will appear on the screen but don't worry about writing it down during your meeting—a summary email will be sent each day which will include contact information for all of your Live Online! Reverse Expo meetings.
- Suppliers. Bring your best "elevator pitch" and a warm smile. Share your
 product or service and allow time for the Provider to share their needs—
 you may be able to meet them in a way you did not initially anticipate.
- Providers. Be honest about whether each product or service will meet your needs; if you express interest to a Supplier during a meeting, be prepared for and please respond to follow up communication from them.

System Requirements

- Desktop Windows 10 & MacOS 10.7 Mojave
 4th gen Intel Core i3, 4GB Ram
 - Google Chrome (preferred)
 - Firefox
 - Microsoft Edge Chromium
 - Safari 11+
- Mobile Android 7.0
 - Google Chrome
- Mobile iOS 12.2
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Special thanks to each Provider for joining our

2021 Fall Hospital Pharmacy
ONLINE
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Please Note Registration is still open and this list is growing every day. The conference book will be updated weekly, but in the meantime, please visit the Confirmed Provider page on our website to see a real-time list of Provider attendees.

Acurity, Inc., New York, NY, David Grish, VP, Client Services

Adirondack Health, Saranac Lake, NY, David Coriale, Director of Pharmacy

Advent Health-Carrollwood, Tampa, FL, David Halterman, Director of Pharmacy

AdventHealth, Tampa, FL, Neil Bulich, PharmD. MBA., Div Director of Pharmacy Services

AdventHealth, Maitland, FL, Shara Hutchinson, PharmD MS BCPS, Population Health Service Org Pharmacy Manager

AdventHealth, Altamonte Springs, FL, Richard Montgomery, BSPharm, MBA, Contracts and Operations Manager - Pharmacy

AdventHealth, Sanford, FL, Trenia Yielding, PharmD, Executive Director of Pharmacy

AdventHealth Central Texas (AHS), Killeen, TX, Jerry King, RPh, MBA, Director of Pharmacy

AdventHealth Daytona Beach, Daytona Beach, FL, Marshall Hughey, Director of Pharmacy

AdventHealth for Children, Orlando, FL, Michael Kalita, Director of Pharmacy

AdventHealth North Pinellas, Tarpon Springs, FL, George Malone, PharmD, Director of Pharmacy

AdventHealth Orlando, Orlando, FL, Steven Allison, Executive Director of Pharmacy

AdventHealth Orlando, Orlando, FL, Zachary Hagen, Pharmacy Supply Chain Coordinator

AdventHealth Palm Coast, Palm Coast, FL, Wayne Taylor, Pharm D, Director of Pharmacy

AdventHealth Sebring, Sebring, FL, Heather Upchurch, Pharm.D., Director of Pharmacy

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Administration¹:

- Feraheme only requires 2 infusions limiting the number of visits
- · No pre-treatment or test dose is required

Dosing¹:

· Feraheme infusions can be dosed as early as 3 days apart, allowing for a complete course of therapy in less than a week

Management of materials¹:

- Feraheme can be mixed with 0.9% NaCl (normal saline) or 5% dextrose
- · Feraheme can be diluted in a range of volumes from 50 - 200mL
- Once diluted, Feraheme can be stored at room temperature for up to 4 hours or refrigerated for up to 48 hours
- . Many of AMAG's commercial supply chain partners are located within North America, and we currently have adequate stock of all our products

 $\textbf{FERAHEME}^{\texttt{o}} \ (\textbf{ferumoxytol injection}), \textbf{for intravenous use Brief Summary:}$ Consult the package insert for complete prescribing information

WARNING: RISK FOR SERIOUS HYPERSENSITIVITY/ ANAPHYLAXIS REACTIONS

Fatal and serious hypersensitivity reactions including anaphylaxis have occurred in patients receiving Feraheme. Initial symptoms may include hypotension, syncope, unresponsiveness, cardiac/cardiorespiratory arrest.

- Only administer Feraheme as an intravenous infusion over at least 15 minutes and only when personnel and therapies are immediately avail for the treatment of anaphylaxis and other hypersensitivity reactions.
- Observe for signs or symptoms of hypersensitivity reactions during and for at least 30 minutes following Feraheme infusion including monitoring of blood pressure and pulse during and after Feraheme administration.
- Hypersensitivity reactions have occurred in patients in whom a previou Feraheme dose was tolerated.

INDICATIONS AND USAGE: Feraheme is indicated for the treatment of iron iciency anemia (IDA) in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron, or who have chronic kidney disease (CKD).

CONTRAINDICATIONS: Feraheme is contraindicated in patients with known hypersensitivity to Feraheme or any of its components or have a history of allergic reaction to any intravenous iron product.

WARNINGS AND PRECAUTIONS, Serious Hypersensitivity Reactions: Fatal and serious hypersensitivity reactions including anaphylaxis, presenting with cardiac/cardiorespiratory arrest, clinically significant hypotension, syncope, or unresponsiveness have occurred in patients receiving Feraheme. Other adverse reactions potentially associated with hypersensitivity have occurred (pruritus, rash, urticaria, and wheezing). These reactions have occurred following the first dose or subsequent doses in patients in whom a previous Feraheme dose was tolerated.

Patients with a history of multiple drug allergies may have a greater risk of anaphylaxis with parenteral iron products. Carefully consider the potential risks and benefits before administering Feraheme to these patients.

Only administer Feraheme as an intravenous infusion over at least 15 minutes and only when personnel and therapies are immediately available for the treatment of anaphylaxis and other hypersensitivity reactions. Closely observe patients for signs and symptoms of hypersensitivity including monitoring of blood pressure and pulse during and after Feraheme administration for at least 30 minutes and until clinically stable following completion of each infusion.

In a clinical study in patients with IDA, regardless of etiology, hypersensitivity reactions were reported in 0.4% (4/997) of subjects receiving Feraheme administered as intravenous infusion over at least 15 minutes. These included one patient with severe hypersensitivity reaction and three patients with moderate hypersensitivity reactions.

In clinical studies predominantly in patients with IDA and CKD, serious hypersensitivity reactions were reported in 0.2% (4/1.806) of subjects receiving Feraheme (administered as a rapid intravenous injection – prior method of administration no longer approved). Other adverse reactions potentially associated with hypersensitivity (e.g., pruritus, rash, urticaria or wheezing) were reported in 3.5% (63/1,806) of these subjects.

In the post-marketing experience, fatal and serious anaphylactic type reactions presenting with cardiac/ cardiorespiratory arrest, clinically significan t hypote syncope, and unresponsiveness have been reported. Elderly patients with multiple or serious co-morbidities who experience hypersensitivity reactions and/or hypote following administration of Feraheme may have more severe outcomes.

Hypotension: Feraheme may cause clinically significant hypotension.

In a clinical study with Feraheme in patients with IDA, regardless of etiology, moderate hypotension was reported in 0.2% (2/997) of subjects receiving Feraheme administered as intravenous infusion over at least 15 minute

FERAHEME® provides established efficacy and safety profile, flexible scheduling

FERAHEME Delivers 1 Gram of Iron in Just 2 Infusions as early as 3 days apart

Flexible scheduling gives your patients the freedom to receive the iron they need as early as 3 days

Fe 1 GRAM





In clinical studies in patients with IDA and CKD, hypotension was reported in 1.9% (35/1,806) of subjects, including three patients with serious hypotensive reactions, who had received Feraheme as a rapid intravenous injection (prior method of administration no longer approved).

Hypotension has also been reported in the post-marketing experience. Monitor patients for signs and symptoms of hypotension following each Feraheme administration

Iron Overload: Excessive therapy with parenteral iron can lead to excess storage of iron with the possibility of iatrogenic hemosiderosis. Regularly monitor the hematologic response during parenteral iron therapy. Do not administer Feraheme to patients with iron overload. In the 24 hours following administration of Feraher laboratory assays may overestimate serum iron and transferrin bound iron by also measuring the iron in the Feraheme complex.

Magnetic Resonance (MR) Imaging Test Interference: Administration of Feraheme may transiently affect the diagnostic ability of MR imaging. Conduct anticipated MR imaging studies prior to the administration of Feraheme. Alteration of MR imaging studies may persist for up to 3 months following the last Feraheme dose. If MR imaging is required within 3 months after Feraheme administration use T1- or proton density-weighted MR pulse sequences to minimize the Feraheme effects; MR imaging using T2-weighted pulse sequences should not be performed earlier than 4 weeks after the administration of Feraheme. Maximum alteration of vascular MR imaging is anticipated to be evident for 1 - 2 days following Feraheme

Feraheme will not interfere with X-ray, computed tomography (CT), positron emission tomography (PET), single photon emission computed tomography (SPECT), ultrasound or nuclear medicine imaging.

 $\label{eq:adverse} \textbf{ADVERSE REACTIONS:} \ \text{The following serious adverse reactions are described}$ elsewhere in the labeling: Serious Hypersensitivity Reactions, Hypotension, Iron Overload, Magnetic Resonance (MR) Imaging Test Interference

Clinical Trial Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In clinical studies, 3,968 subjects were exposed to Feraheme. Of these subjects 31% were male and the median age was 54 years (range of 18 to 96 years).

The data described below reflect exposure to Feraheme in 997 patients exposed to a 1.02 g course of ferumoxytol administered as two 510 mg intravenous (IV) doses: 992 subjects (99.5%) received at least 1 complete dose of ferumoxytol and 946 subjects (94.9%) received 2 complete doses. The mean cumulative IV Iron exposure was 993.80 ±119.085 mg.

The safety of Feraheme was studied in a randomized, multicenter, double-blind clinical trial in patients with IDA (IDA Trial 3). In this trial, patients were randomized to two intravenous infusions of 510 mg (1.02 g) of Feraheme (n=997), or two intravenous infusions of 750 mg (1.500 g) of ferric carboxymaltose (FCM) (n=1000). Both intravenous irons were infused over a period of at least 15 minutes. Most patients received their second infusion of Feraheme and FCM 7(+1) days after

The mean (SD) age of the study population (N=1997) was 55.2 (17.16) vears. The majority of patients were female (76.1%), white (71.4%) and non-Hispa The mean (SD) hemoglobin at baseline for all patients was 10.4 (1.5) g/dl.

Serious adverse events were reported in 3.6% (71/1997) of ferumoxytol- and FCM-treated patients. The most common (≥2 subjects) serious AEs reported in Feraheme-treated patients were syncope, gastroenteritis, seizure, pneumonia, hemorrhagic anemia, and acute kidney injury. In FCM-treated patients the mos common (≥2 subjects) serious AEs were syncope, cardiac failure congestive, angina

Adverse reactions related to Feraheme and reported by \geq 1% of Feraheme-treated patients in IDA Trial 3 following administration of Feraheme 2 x 510 mg (N=997)

or ferric carboxymaltose 2 x 750 mg (N =1000) were headache (3.4% Feraheme 3.1% ferric carboxymaltose), nausea (1.8, 3.4), dizziness (1.5, 1.6), fatigue (1.5, 1.2), diarrhea (1, 0,8), and back pain (1, 0,4),

In IDA Trial 3, adverse reactions leading to treatment discontinuation and occurring in ≥ 2 Feraheme-treated patients included arthralgia (0.3%), dyspnea (0.3%), flushing (0.2%), chest discomfort (0.2%), chest pain (0.2%), nausea (0.2%), back pain (0.2%), dizziness (0.2%) and headache (0.2%).

Across two clinical trials in patients with IDA (IDA Trial 1 and 2), patients were randomized to: two injections (rapid intravenous injection - prior method of administration no longer approved) of 510 mg of Feraheme (n=1,014), placebo (n=200), or five injections/infusions of 200 mg of iron sucrose (n=199). Most patients received their second Feraheme injection 3 to 8 days after the first injection. Adverse reactions related to Feraheme and reported by ≥ 1% of Feraheme-treated patients in these trials were similar to those seen in Trial 3.

In Trials 1 and 2, adverse reactions leading to treatment discontinuation and occurring in ≥ 2 Feraheme-treated patients included hypersensitivity (0.6%) hypotension (0.3%), and rash (0.2%).

In addition, a total of 634 subjects enrolled in and completed participation in a Phase 3 open label extension study. Of these, 337 subjects met IDA treatment criteria and received Feraheme. Adverse reactions following this repeat Feraheme dosing were generally similar in type and frequency to those observed after the first two intravenous injections.

Across three randomized clinical trials in patients with IDA and CKD (CKD Trials 1, 2, and 3), a total of 605 patients were exposed to two injections of 510 mg of Feraheme and a total of 280 patients were exposed to 200 mg/day of oral iron for 21 days. Most patients received their second Feraheme injection 3 to 8 days after the first injection.

Adverse reactions related to Feraheme and reported by ≥ 1% of Feraheme-treated patients in the CKD randomized clinical trials following administration of Feraheme 2 x 510 mg (n=605) or oral iron (n=280) were nausea (3.1% Feraheme, 7.5% oral iron), dizziness (2.6, 1.8), hypotension (2.5, 0.4), peripheral edema (2, 3.2), headache (1.8, 2.1), edema (1.5, 1.4), vomiting (1.5, 5), abdominal pain (1.3, 1.4), chest pain (1.3, 0.7), cough (1.3, 1.4), pruritus (1.2, 0.4), pyrexia (1, 0.7), back pain (1, 0), muscle spasms (1, 1.4), dyspnea (1, 1.1), and rash (1, 0.4). Diarrhea (4%), constipation (2.1%) and hypertension (1%) have also been reported in Feraheme-treated patients.

In these clinical trials in patients with IDA and CKD, adverse reactions leading to treatment discontinuation and occurring in ≥ 2 Feraheme-treated patients included hypotension (0.4%), chest pain (0.3%), and dizziness (0.3%).

Following completion of the controlled phase of the trials, 69 patients received two additional 510 mg intravenous injections of Feraheme (for a total cumulative dose of 2.04 a). Adverse reactions following this repeat Feraheme dosing were similar in character and frequency to those observed following the first two intravenous injections.

Postmarketing Experience: Because adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure

The following serious adverse reactions have been reported from the post-marketing experience with Feraheme: fatal, life-threatening, and serious anaphylactic-type actions, cardiac/cardiorespiratory arrest, clinically significant hypotension, syncope, unresponsiveness, loss of consciousness, tachycardia/rhythm abnormalities, angioedema, ischemic myocardial events, congestive heart failure, pulse absent, and cyanosis. These adverse reactions have usually occurred within 30 minutes after the administration of Feraheme. Reactions have occurred following the first dose or subsequent doses of Feraheme

See full Prescribing Information for Feraheme available at www.feraheme.com.

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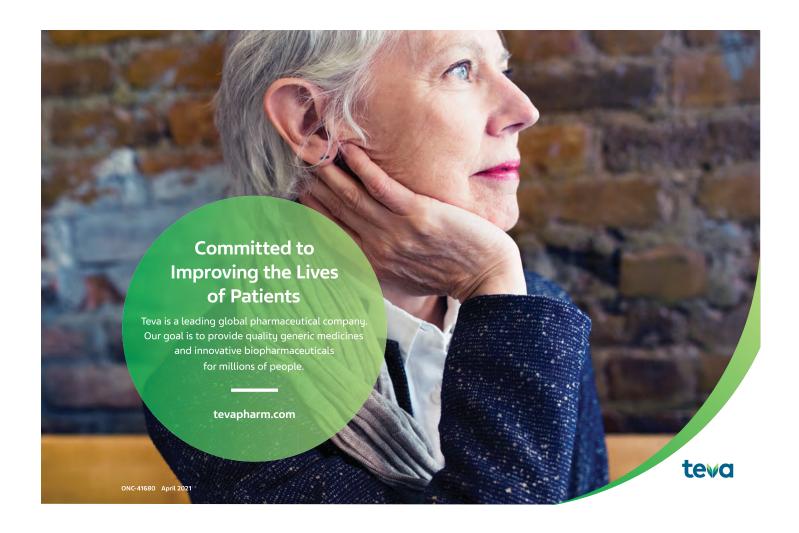
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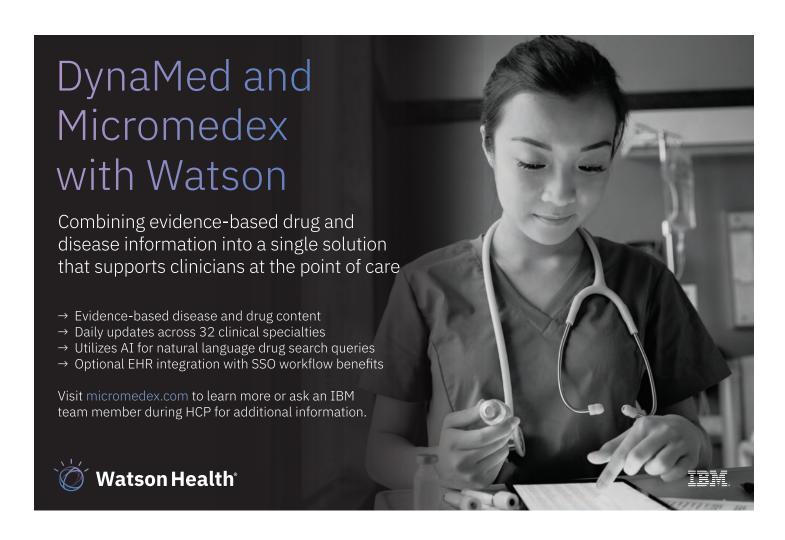
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