Leiters Health
QUALITY COMPOUNDING FOR LIFE™

Bupivacaine Dexamethasone Plus Epinephrine Pre-filled Syringes

THE OPIOID EPIDEMIC IN AMERICA.

Navigating patient care and pain management during the opioid epidemic is challenging. America's hospitals, health systems and healthcare providers are battling on the front lines and are increasingly turning to opioid-free pain management solutions.

To assist in this crisis, and meet critical customer needs, Leiters Health, a trusted FDA registered 503B outsourcing provider, has expanded its portfolio to include an opioid-free nerve block agent. This patent-pending combination sterile preparation consists of three non-opioid drugs in a ready-to-administer syringe: bupivacaine HCl, dexamethasone sodium phosphate, and epinephrine.

> *"We required a compounding pharmaceutical company that received high grades in quality, compliance, consistency, service, and standardization. This endeavor could not produce variation in the product. Our decision to choose Leiters Health ultimately came down to their overall expertise in sterile manufacturing, quality, compliance, and capacity."*
>
> *John Feucht, Vice President of Pharmacy Services, Summa Health*

PRODUCT DETAILS:

- Sterile, ready-to-administer, compounded Bupivacaine HCl 0.375%, Dexamethasone Phosphate 0.01%, PLUS Epinephrine 1:200,000, preservative-free
- 30 mL fill in a 35 mL syringe
- 90 day Beyond Use Date (BUD)[1]
- Product Number F3157
- NDC Number 71449-134-32
- 10 syringes per pack
- Compatible with the Kit Check automated medication tray management system

Visit leiters.com to download the published Pharmacy Case Study, "Summa Health and Leiters Health Collaborate to Reduce Opioid Use".

This case study details one health system's journey to reduce opioid use and the benefits of partnering with an FDA-registered 503B outsourcing facility.

Orders & Inquiries 800.292.6772 www.leiters.com info@leiters.com

Leiters Health

About Leiters Health

Leiters Health, founded in 1926, provides hospitals, surgery centers, clinics and physician offices access to vital medicines. Our team of experts in sterile pharmaceutical manufacturing, repackaging, and compounding provide a sophisticated understanding of what it takes to elevate quality and consistency of supply. We combine our team, our robust processes and our state-of-the-art outsourcing facility to ensure the highest quality products and services.

THROUGH 3 KEY PILLARS, PEOPLE, PLACE AND PRODUCT, LEITERS HEALTH IS ELEVATING THE STANDARDS IN PHARMACEUTICAL OUTSOURCING.

PEOPLE

Let our team become an extension of your pharmacy. Our multi-disciplinary team of professionals includes quality assurance experts, microbiologists, pharmacists, ophthalmic specialists and health system pharmacy experts.

- We have a legacy of deep experience in current Good Manufacturing Practices (cGMP), sterile pharmaceutical product development, manufacturing, compounding, and repackaging.
- Our leadership team has relevant industry experience with sterile pharmaceutical companies, hospital pharmacies, regulatory compliance, and academia.
- Our customer experience team of regional based account representatives, account managers and customer service specialists work together to provide you with consistent and reliable service.

PLACE

With increasing regulatory pressure, there is a growing need for higher standards in pharmaceutical outsourcing. Our state-of-the-art facility was designed to exceed traditional outsourcing facilities and ensures quality, consistency, and compliance with all released products.

- FDA-registered and inspected, cGMP compliant 503B outsourcing provider.
- Licensed to ship to all 50 states (+ the District of Columbia).
- State-of-the-art equipment and automation is used throughout our sterile manufacturing process.

PRODUCT

Leiters Health offers a wide range of ready-to-administer compounded sterile preparation and pharmacy services including pre-filled syringes, IV bags and vials, non-opioid pain solutions, and ophthalmic medications and services including, an FDA-Compliant Repackaged Avastin® service.

- All sterile preparations are produced under 503B of the FD&C act (503B Guidance), following current Good Manufacturing Practices (cGMP) and meet or exceed USP <797>.
- Full microbiological and chemistry testing is completed prior to each batch being released. This includes sterility, endotoxin, potency, identification, impurities, particulate (subvisible), visual appearance and pH testing.

QUALITY. COMPLIANCE. CONSISTENCY.