Leiters.

COMPOUNDING HEALTH™

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, 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.

Visit leiters.com to download the recently published Pharmacy Case Study, "Summa Health and Leiters 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.

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

"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 ultimately came down to their overall expertise in sterile manufacturing, quality, compliance, and capacity."

John Feucht, Vice President of Pharmacy Services, Summa Health

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ABOUT LEITERS

Leiters, founded in 1926, provides hospitals, surgery centers, clinics and physician offices access to high-quality compounded sterile preparations. 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 is elevating the standards in pharmaceutical outsourcing.

PEOPLE

Let our team become an extension of your own. Our multi-disciplinary team of professionals consists of quality assurance experts, microbiologists, pharmacists, ophthalmology 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

This is the place where quality means something. 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 including, vertical laminar flow hoods, a biodecontamination system, negative-pressure isolators, laboratory fume hoods, biosafety cabinets, automated syringe filling and inspection and automated labeling machines.

PRODUCT

Leiters offers a wide range of 503B ready-to-administer compounded sterile preparations.

- 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>.
- Independent laboratory testing of chemical and microbiological characteristics including identification, bioburden and endotoxin of all incoming active and inactive ingredients.
- Stability testing is performed before producing batches.
- Microbiological and chemistry testing (including sterility, endotoxin, potency, identification, impurities, particulate-sub visible, visual appearance, and pH testing) is completed before any product release.
- Beyond Use Dates (BUDs) are established based on product-specific stability testing of both chemical and microbiological characteristics.
- A Certificate of Analysis (CoA), detailing all the testing performed, is provided with every shipment.

Quality. Compliance. Consistency.

 [1] Beyond Use Date is from date of compounding. Customer represents that the 503B outsourced drug will be administered or dispensed only to a patient for whom there is a clinical difference from an approved drug, as determined by the prescribing practitioner for that patient.