

2024 CATALOG

Hospital and Ophthalmic 503B Products and Services



Elevating the standards in 503B pharmaceutical outsourcing.

The world of healthcare is constantly changing. With increasing regulatory pressure, treatment shortages and the need to do more with less, high quality pharmaceutical outsourcing is more important than ever.

Leiters Health, founded in 1926, is an FDA-registered 503B outsourcing provider of hospital and ophthalmic compounded sterile preparations and pharmacy services.

Our team of experts in sterile pharmaceutical manufacturing, repackaging and quality assurance provide a sophisticated understanding of what it takes to elevate quality and consistency of supply in outsourcing. We combine our team, our robust processes and our state-of-the-art facility to ensure the highest quality vital medications for you and your patients.

To learn more or
schedule a site visit:



800.292.6772



www.leiters.com



info@leiters.com



Overview

HOSPITAL AND SURGERY CENTER PRODUCTS AND SERVICES

- Prefilled syringes including PCA (patient-controlled analgesia).
- IV bags and vials.
- Surgical Pain Services portfolio including opioid free medications.
- Pharmacy fill service for the Avanos Medical ON-Q* Pain Relief System.

OPHTHALMIC PRODUCTS AND SERVICES

- Prefilled syringes, vials, and dropper bottles.
- Injections, antibiotics and dilating agents.
- FDA-Compliant Repackaged Avastin® Service.

QUALITY COMPOUNDING FOR LIFE

- FDA-registered and inspected, cGMP compliant 503B outsourcing provider.
 - Licensed by 50 State Boards of Pharmacy (+ the District of Columbia).
 - Multi-disciplinary team with deep experience in cGMP, sterile pharmaceutical manufacturing, repackaging, pharmacy and compounding.
 - Providing vital medicines and pharmacy services across the continuum of healthcare including hospitals, surgery centers, clinics and physician offices.
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Ophthalmic Services

OPHTHALMIC INJECTIONS

Item Number	NDC	Item Description	Fill	Container	BUD (days) ¹	Pack size
F1012	71449-090-42	Lidocaine HCl 1% / Phenylephrine HCl 1.5%	1 mL	2 mL vial	180	10
F1016	71449-096-42	Moxifloxacin 1 mg/mL	1 mL	2 mL vial	180	10
F1018	71449-097-42	Moxifloxacin 5 mg/mL	1 mL	2 mL vial	180	10

FDA-COMPLIANT REPACKAGED BEVACIZUMAB (AVASTIN®) SERVICE

Item Number	NDC	Item Description	Fill	Container	BUD (days) ¹	Pack size
F1001	71449-091-43	Bevacizumab 2.5 mg/0.1 mL (repackaged)	0.1 mL	1 mL syringe	90	10
F1002	71449-091-44	Bevacizumab 3.25 mg/0.13 mL (repackaged)	0.13 mL	1 mL syringe	90	10
F1042	71449-091-22	Bevacizumab 2 mg/0.08 mL (repackaged), StaClear® syringe	0.08 mL	0.25 mL syringe	150	10
F1045	71449-091-90	Bevacizumab 2.75 mg/0.11 mL (repackaged), StaClear® syringe	0.11 mL	0.25 mL syringe	150	10

OPHTHALMIC SOLUTIONS

Item Number	NDC	Item Description	Fill	Container	BUD (days) ¹	Pack size
F1003	71449-092-45	Cyclopentolate HCl 1%/Tropicamide 1%/Phenylephrine HCl 2.5%	1 mL	11 mL dropper	120	10
F1004	71449-092-46	Cyclopentolate HCl 1%/Tropicamide 1%/Phenylephrine HCl 2.5%	5 mL	11 mL dropper	120	1
F1008*	71449-093-47	Cyclopentolate HCl 1%/Tropicamide 1%/Phenylephrine HCl 2.5%	10 mL	11 mL dropper	120	1
F1019*	71449-098-48	Tropicamide 1%/Phenylephrine HCl 2.5%	2 mL	11 mL dropper	150	10
F1020*	71449-098-46	Tropicamide 1%/Phenylephrine HCl 2.5%	5 mL	11 mL dropper	150	1
F1021	71449-098-47	Tropicamide 1%/Phenylephrine HCl 2.5%	10 mL	11 mL dropper	150	1

Hospital and Surgery Center Services

OR SYRINGES

Item Number	NDC	Item Description	Fill	Container	BUD (days) ¹	Pack size
F3139*	71449-116-27	Adenosine 1 mg/mL, Lidocaine HCl 1 mg/mL, Magnesium Sulfate 100 mg/mL (FDP)	40 mL	60 mL	90	5
F3056	71449-015-06	Atropine Sulfate 0.4 mg/mL (FDP)	2.5 mL	3 mL syringe	180	5
F3113	71449-106-11	Ephedrine Sulfate 5 mg/mL (FDP)	5 mL	5 mL syringe	180	5
F3115	71449-106-15	Ephedrine Sulfate 5 mg/mL (FDP)	10 mL	10 mL syringe	180	5
F3063*	71449-020-15	Epinephrine 100 mcg/mL (API)	10 mL	10 mL syringe	66	5
F3050	71449-013-05	Fentanyl Citrate 50 mcg/mL, PF (API)	2 mL	3 mL syringe	90	5
F3053*	71449-013-15	Fentanyl Citrate 50 mcg/mL, PF (API)	10 mL	10 mL syringe	120	5
F3104*	71449-104-07	Glycopyrrolate 0.2 mg/mL (FDP)	3 mL	3 mL syringe	180	5
F3105*	71449-104-05	Glycopyrrolate 0.2 mg/mL (FDP)	2 mL	3 mL syringe	180	5
F3106	71449-104-11	Glycopyrrolate 0.2 mg/mL (FDP)	5 mL	5 mL syringe	180	5
F3068	71449-023-07	Lidocaine HCl 1%, PF (API)	3 mL	3 mL syringe	180	5
F3069	71449-002-11	Lidocaine HCl 1%, PF (API)	5 mL	5 mL syringe	180	5
F3073	71449-024-07	Lidocaine HCl 2%, PF (API)	3 mL	3 mL syringe	180	5
F3074	71449-024-11	Lidocaine HCl 2%, PF (API)	5 mL	5 mL syringe	180	5
F3064*	71449-021-05	Morphine Sulfate 1 mg/mL, PF (API)	2 mL	3 mL syringe	180	5
F3091*	71449-021-11	Morphine Sulfate 1 mg/mL, PF (API)	5 mL	5 mL syringe	180	5
F3103*	71449-103-11	Neostigmine Methylsulfate 1 mg/mL (FDP)	5 mL	5 mL syringe	120	5
F3145	71449-125-11	Neostigmine Methylsulfate 1 mg/mL, PF (API)	5 mL	5 mL syringe	180	5
F3001	71449-001-11	Phenylephrine HCl 100 mcg/mL (FDP)	5 mL	5 mL syringe	180	5
F3002	71449-001-15	Phenylephrine HCl 100 mcg/mL (FDP)	10 mL	10 mL syringe	180	5
F3012	71449-004-11	Rocuronium Bromide 10 mg/mL (FDP)	5 mL	5 mL syringe	180	5
F3013	71449-004-15	Rocuronium Bromide 10 mg/mL (FDP)	10 mL	10 mL syringe	180	5
F3107*	71449-105-11	Succinylcholine Chloride 20 mg/mL (FDP)	5 mL	5 mL syringe	90	5
F3109	71449-105-15	Succinylcholine Chloride 20 mg/mL (FDP)	10 mL	10 mL syringe	90	5
F3146	71449-126-15	Succinylcholine Chloride 20 mg/mL, PF (API)	10 mL	10 mL syringe	100	5

* Please reach out to your local representative or contact us at 800.292.6772 for current availability.
 PF = preservative-free API: Active Pharmaceutical Ingredient | FDP: Finished Dose Product

Hospital and Surgery Center Services

SURGICAL PAIN SERVICES

Item Number	NDC	Item Description	Fill	Container	BUD (days) ¹	Pack size
F3099*	71449-075-32	Bupivacaine HCl 0.375% Dexamethasone Phosphate 0.01% (API)	30 mL	35 mL syringe	150	10
F3164	71449-134-24	Bupivacaine HCl 0.375% Dexamethasone Phosphate 0.01% and Epinephrine 1:200,000, PF (API)	30 mL	50 mL syringe	90	10
F3151	71449-131-11	Dexmedetomidine HCl 4 mcg/mL, PF (API)	5 mL	5 mL syringe	120	5
F3152*	71449-131-18	Dexmedetomidine HCl 4 mcg/mL, PF (API)	20 mL	20 mL syringe	120	5
F3154	71449-131-15	Dexmedetomidine HCl 4 mcg/mL, PF (API)	10 mL	10 mL syringe	120	5
F3054	71449-013-32	Fentanyl Citrate 50 mcg/mL, PF, PCA (API)	30 mL	35 mL syringe	180	5
F3061	71449-018-32	Hydromorphone HCl 1 mg/mL, PCA (API)	30 mL	35 mL syringe	180	5
F3080	71449-068-11	Ketamine HCl 10 mg/mL (API)	5 mL	5 mL syringe	180	5
F3156	71449-068-32	Ketamine HCl 10 mg/mL, PCA (API)	30 mL	35 mL syringe	180	5
F3058*	71449-016-32	Midazolam 5mg/mL, PCA (FDP)	30 mL	35 mL syringe	180	5
F3150	71449-130-32	Midazolam 5mg/mL, PCA (API)	30 mL	35 mL syringe	180	5
F3065	71449-022-32	Morphine Sulfate 5 mg/mL, PCA, PF (API)	30 mL	35 mL syringe	180	5
F3087*	71449-070-18	Ropivacaine HCl 0.2%, PF (API)	20 mL	20 mL syringe	180	5
F3158	71449-070-25	Ropivacaine HCl 0.2%, PF (API)	50 mL	50 mL syringe	180	5

ON-Q* PAIN RELIEF SYSTEM

Item Number	NDC	Item Description	Fill	Container	BUD (days) ¹	Pack size
K-F9102*	71449-078-51	Bupivacaine HCl 0.125% (1.25 mg/mL), PF (API)	550 mL [†]	ON-Q* CB004	90	1
K-F9202	71449-079-51	Ropivacaine HCl 0.2% (2 mg/mL), PF (API)	550 mL [†]	ON-Q* CB004	90	1
K-F9206	71449-079-55	Ropivacaine HCl 0.2% (2 mg/mL), PF (API)	550 mL [†]	ON-Q* CB006	90	1
K-F9208	71449-079-57	Ropivacaine HCl 0.2% (2 mg/mL), PF (API)	750 mL [†]	ON-Q* CB6004	90	1
K-F9210	71449-079-59	Ropivacaine HCl 0.2% (2 mg/mL), PF (API)	750 mL [†]	ON-Q* CB6007	90	1
K-F9214*	71449-079-34	Ropivacaine HCl 0.2% (2 mg/mL), PF (API)	550 mL [†]	ON-Q* P400X8	90	1

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Hospital and Surgery Center Services

INTRAVENOUS (IV) BAGS

Item Number	NDC	Item Description	Fill	Container	BUD (days) ¹	Pack size
F3337	71449-124-83	Ropivacaine HCl 0.2% (2 mg/mL) in 0.9% Sodium Chloride, PF (API)	500 mL	500 mL bag	180	6
F3340	71449-124-91	Ropivacaine HCl 0.2% (2 mg/mL) in 0.9% Sodium Chloride, PF (API)	1000 mL	1000 mL bag	180	6

VIALS

Item Number	NDC	Item Description	Fill	Container	BUD (days) ¹	Pack size
F4004*	71449-133-39	Norepinephrine Bitartrate 16 mg (2 mg/mL) (API)	8 mL	10 mL vial	90	10
F4002*	71449-133-95	Norepinephrine Bitartrate 4 mg (2 mg/mL) (API)	2 mL	5 mL vial	90	10
F4003*	71449-133-97	Norepinephrine Bitartrate 8 mg (2 mg/mL) (API)	4 mL	5 mL vial	90	10

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Leiters Health is a trusted FDA-registered 503B outsourcing provider of 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 in pharmaceutical outsourcing. We combine a highly experienced team, with robust automated processes, in a state-of-the-art outsourcing facility, to ensure delivery of the highest quality medicines. All sterile preparations are produced under the Human Drug Outsourcing Facilities under 503B of the FD&C Act (503B Guidance) and follow Current Good Manufacturing Practices (cGMP). To learn more about how Leiters Health is Compounding Health™ please visit www.leiters.com

NEW FORMULATIONS ARE CONTINUALLY ADDED TO OUR PORTFOLIO. TO INQUIRE ABOUT A SPECIFIC FORMULATION OR PRESENTATION, PLEASE CONTACT US.

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