Ordering and Distribution Information

Xenleta™ (lefamulin)
150 mg injection | 600 mg tablets

XENLETA is available from participating Nabriva wholesalers only. Nabriva has partnered with the following wholesalers to stock and ship XENLETA. Please note that Nabriva does not endorse the use of any particular wholesaler, and one is not preferred over the others.

Product and Ordering Information

	Xenleta™ (lefamulin) Tablets, 600 mg	Xenleta™ (lefamulin) Injection, 150 mg	Diluent for Xenleta™ (lefamulin), 250 mL
NDC Number	10-digit: 72000-110-30 11-digit: 72000-0110-30	10-digit: 72000-120-06 11-digit: 72000-0120-06	10-digit: 72000-030-06 11-digit: 72000-0030-06
Minimum Order Quantity	Bottle of 30 tablets	Carton of 6 vials	Carton of 6 bags
Storage	Controlled Room – between 20° and 25°C (68° – 77°F)	Cold – between 2° and 8°C (36° – 46°F)	Controlled Room – between 20° and 25°C (68° – 77°F)
Carton Dimensions	Bottle Size 1.737D X 3.628H X 1.737W	Carton of 6 3.548D X 3.62H X 2.611W	Carton of 6 bags 12.75D X 4.625H X 6.625W

Wholesalers

Wholesaler Telephone, Fax, and Web Ordering Information	Xenleta™ (lefamulin) Tablets, 600 mg Item Order Number	Xenleta™ (lefamulin) Injection, 150 mg Item Order Number	Diluent for Xenleta™ (lefamulin), 250 mL Item Order Number
ASD Healthcare Phone: 800-746-6273 | Fax: 800-547-9413 Email: asd.customerservice@asdhealthcare.com Web: www.asdhealthcare.com	55560	55561	55559
Cardinal Health Phone: 866-677-4844 | Fax: 877-274-9897 Email: GMB-spd-csorderentry@cardinalhealth.com Web: www.cardinalhealth.com	5564711	5564703	5564695
McKesson Plasma and Biologics Phone: 877-625-2566 | Fax: 888-752-7626 Email: mpborders@mckesson.com Web: connect.mckesson.com	3980885	3980877	3980893
Morris and Dickson Specialty Division Phone: 800-388-3833 | Fax: 318-798-5237 Email: customerservice@morrisdickson.com Web: mdspecialtydist.com	886457	887612	887620

Specialty Retail and Specialty Pharmacy Locator

XENLETA 600 mg tablets are available through designated specialty retail pharmacies and specialty pharmacies. Some hospitals may also be able to dispense XENLETA through their own outpatient pharmacies. Hospital providers with their own in-house specialty pharmacies may also dispense XENLETA. Hospitals should check with their patient's insurance company to identify if a pharmacy can dispense XENLETA. For more information, please call Nabriva RX Connect at 1-855-5NABRIVA (Option 3) for assistance or visit XENLETA.com/pharmacy.

Nabriva RX Connect™

Nabriva RX Connect
Eastpoint Parkway, Louisville, KY 40223 | Phone number: 1-855-5NABRIVA (Option 3) | Fax: 1-866-867-9868

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Indication and Important Safety Information

Indication

XENLETA is a pleuromutilin antibacterial indicated for the treatment of adults with community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae,* and *Chlamydophila pneumoniae.*

Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of XENLETA and other antibacterial drugs, XENLETA should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

Important Safety Information

CONTRAINDICATIONS

XENLETA is contraindicated in patients with known hypersensitivity to XENLETA or pleuromutilins.

XENLETA tablets are contraindicated for use with CYP3A4 substrates that prolong the QT interval.

WARNINGS AND PRECAUTIONS

XENLETA has the potential to prolong the QT interval. Avoid XENLETA in patients with known QT prolongation, ventricular arrhythmias, and patients receiving drugs that may prolong the QT interval.

Based on animal studies, XENLETA may cause fetal harm. Advise females of reproductive potential of the potential risk to the fetus and to use effective contraception.

Clostridium difficile-associated diarrhea (CDAD) has been reported with nearly all systemic antibacterial agents, including XENLETA, with severity ranging from mild diarrhea to fatal colitis. Evaluate if diarrhea occurs.

ADVERSE REACTIONS

The most common adverse reactions (≥2%) for (a) XENLETA Injection are administration site reactions, hepatic enzyme elevation, nausea, hypokalemia, insomnia, and headache and (b) XENLETA Tablets are diarrhea, nausea, vomiting, and hepatic enzyme elevation.

USE IN SPECIFIC POPULATIONS

In patients with severe hepatic impairment, reduce the dosage of XENLETA Injection to 150 mg infused over 60 minutes every 24 hours. XENLETA Tablets are not recommended in patients with moderate or severe hepatic impairment due to insufficient information to provide dosing recommendations.

Avoid XENLETA Injection and Tablets with concomitant strong or moderate CYP3A or P-gp inducers. Monitor for reduced efficacy of XENLETA.

Avoid XENLETA Tablets with strong CYP3A or P-gp inhibitors.

Monitor for adverse reactions of sensitive CYP3A substrates administered with XENLETA Tablets.

XENLETA has not been studied in pregnant women. Verify pregnancy status in females prior to initiating XENLETA and advise females to use contraception during treatment and for 2 days after the final dose. Lactating women should pump and discard milk for the duration of treatment with XENLETA and for 2 days after the final dose.

To report SUSPECTED ADVERSE REACTIONS, or administration during pregnancy, contact Nabriva Therapeutics US, Inc. at 1-855-5NABRIVA or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Full Prescribing Information for XENLETA.

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