Pombiliti® (cipaglucosidase alfa-atga) + Opfolda® (miglustat) 65 mg capsules

PRODUCT ORDERING INFORMATION

THE FIRST AND ONLY 2-COMPONENT THERAPY IN LOPD

INDICATION

POMBILITI® (cipaglucosidase alfa-atga) in combination with OPFOLDA® (miglustat) is indicated for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy (ERT).

IMPORTANT SAFETY INFORMATION

WARNING: WARNING: SEVERE HYPERSENSITIVITY REACTIONS, INFUSION-ASSOCIATED REACTIONS, AND RISK OF ACUTE CARDIORESPIRATORY FAILURE IN SUSCEPTIBLE PATIENTS

See full prescribing information for complete boxed warning

HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS

Appropriate medical support measures, including cardiopulmonary resuscitation equipment, should be readily available. If a severe hypersensitivity reaction occurs, POMBILITI should be discontinued immediately and appropriate medical treatment should be initiated.

INFUSION-ASSOCIATED REACTIONS (IARS)

If severe IARs occur, immediately discontinue POMBILITI and initiate appropriate medical treatment.

RISK OF ACUTE CARDIORESPIRATORY FAILURE IN SUSCEPTIBLE PATIENTS

Patients susceptible to fluid volume overload, or those with acute underlying respiratory illness or compromised cardiac or respiratory function, may be at risk of serious exacerbation of their cardiac or respiratory status during POMBILITI infusion.

Please see IMPORTANT SAFETY INFORMATION on pages 2 and 3 and full Prescribing Information, including BOXED WARNING, for POMBILITI and full Prescribing Information for OPFOLDA, also available at PombilitiOpfoldaHCP.com.

Amicus Therapeutics

POMBILITI
bis-M6P ENRICHED ENZYME

HOW SUPPLIED

Description	POMBILITI (cipaglucosidase alfa-atga) for injection: 105 mg of cipaglucosidase alfa-atga as a lyophilized powder in a single-dose vial for reconstitution.

NDC* Numbers	Carton Descriptions	Dimensions
71904-**0**200-01	One 105 mg single-dose vial in a single carton	2” x 1.7” x 2.7”
71904-**0**200-02	Ten (10) 105 mg single dose vials in a multipack carton	9” x 3.6” x 2.5”
71904-**0**200-03	Twenty-five (25) 105 mg single dose vials in a multipack carton	9” x 9” x 2.5”

*NDC=National Drug Code. Payer requirements vary. This form is showing a “zero-filled” 11-digit code that meets Health Insurance Portability and Accountability Act (HIPAA) standards. The zero-fill location is indicated in bold.

Storage & Handling	Store refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Do not freeze.

IMPORTANT SAFETY INFORMATION

WARNING: SEVERE HYPERSENSITIVITY REACTIONS, INFUSION-ASSOCIATED REACTIONS, and RISK OF ACUTE CARDIORESPIRATORY FAILURE IN SUSCEPTIBLE PATIENTS HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS

Patients treated with POMBILITI have experienced life-threatening hypersensitivity reactions, including anaphylaxis. Appropriate medical support measures, including cardiopulmonary resuscitation equipment, should be readily available during POMBILITI administration. If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, POMBILITI should be discontinued immediately, and appropriate medical treatment should be initiated. In patients with severe hypersensitivity reaction, desensitization measures to POMBILITI may be considered. The risks and benefits of readministering POMBILITI following severe hypersensitivity reaction should be considered. If mild or moderate hypersensitivity reaction occurs, the infusion rate may be slowed or temporarily stopped. Prior to POMBILITI administration, consider pretreating with antihistamines, antipyretics, and/or corticosteroids.

INFUSION-ASSOCIATED REACTIONS (IARS)

Patients treated with POMBILITI have experienced severe IARs. If severe IARs occur, immediately discontinue the POMBILITI infusion, initiate appropriate medical treatment, and assess the benefits and risks of readministering POMBILITI following severe IARs. If mild or moderate IARs occur regardless of pretreatment, decreasing the infusion rate or temporarily stopping the infusion may ameliorate the symptoms. IARs may still occur in patients after receiving pretreatment.

Patients with an acute underlying illness at the time of POMBILITI infusion may be at greater risk for IARs. Patients with advanced Pompe disease may have compromised cardiac and respiratory function, which may predispose them to a higher risk of severe complications from IARs.

RISK OF ACUTE CARDIORESPIRATORY FAILURE IN SUSCEPTIBLE PATIENTS

Patients susceptible to fluid volume overload, or those with acute underlying respiratory illness or compromised cardiac or respiratory function for whom fluid restriction is indicated may be at risk of serious exacerbation of their cardiac or respiratory status during POMBILITI infusion. More frequent monitoring of vitals should be performed during POMBILITI infusion in such patients.

Please see IMPORTANT SAFETY INFORMATION on pages 2 and 3 and full Prescribing Information, including BOXED WARNING, for POMBILITI and full Prescribing Information for OPFOLDA, also available at PombilitiOpfoldaHCP.com.

OPFOLDA
ORAL STABILIZER

HOW SUPPLIED

Description	OPFOLDA (miglustat) capsules: 65mg

NDC* Numbers	Bottle Descriptions	Dimensions
71904-**0**300-01	4-count bottle	1.5” x 1.5” x 3”
71904-**0**300-02	24-count bottle	1.5” x 1.5” x 3”
71904-**0**300-03	100-count bottle	1.9” x 1.9” x 4.5”

*NDC=National Drug Code. Payer requirements vary. This form is showing a “zero-filled” 11-digit code that meets Health Insurance Portability and Accountability Act (HIPAA) standards. The zero-fill location is indicated in bold.

Storage & Handling	Store at 20°C to 25°C (68°F to 77°F). Excursions are permitted between 15°C to 30°C (59°F to 86°F). Store in the original container to protect from light.

IMPORTANT SAFETY INFORMATION (CONT.)

CONTRAINDICATION

POMBILITI in combination with OPFOLDA is contraindicated in pregnancy.

EMBRYO-FETAL TOXICITY

Based on findings from animal reproduction studies, POMBILITI in combination with OPFOLDA may cause embryo-fetal harm when administered to a pregnant female and is contraindicated during pregnancy. Verify the pregnancy status in females of reproductive potential prior to initiating treatment with POMBILITI in combination with OPFOLDA. Advise females of reproductive potential to use effective contraception during treatment with POMBILITI in combination with OPFOLDA and for at least 60 days after the last dose.

RISKS ASSOCIATED WITH POMBILITI AND OPFOLDA

POMBILITI and OPFOLDA must be administered in combination.

ADVERSE REACTIONS

The most common adverse reactions (≥5%) reported in the pooled safety population of patients treated with POMBILITI in combination with OPFOLDA in the 3 clinical trials were headache, diarrhea, fatigue, nausea, abdominal pain, and pyrexia.

To report SUSPECTED ADVERSE REACTIONS, contact Amicus Therapeutics at 1-877-4AMICUS or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

LACTATION

Advise females that breastfeeding is not recommended while on treatment with POMBILITI in combination with OPFOLDA.

Please see IMPORTANT SAFETY INFORMATION on pages 2 and 3 and full Prescribing Information, including BOXED WARNING, for POMBILITI and full Prescribing Information for OPFOLDA, also available at PombilitiOpfoldaHCP.com.

ORDERING POMBILITI + OPFOLDA

Specialty Distributors	Customer Service Number
Cardinal Health SPD	(855) 855-0708
Cencora (ASD Healthcare, Besse Medical, Oncology Supply)	(800) 746-6273
CuraScript Specialty Distribution	(877) 900-9223
McKesson Plasma and Biologics (MPB)	(877) 625-2566
McKesson Specialty Care Distribution (MSCD)	(800) 482-6700

For your convenience, you may also order through your Specialty Distributor online order platform/portal.

LIMITED SPECIALTY PHARMACY NETWORK FOR POMBILITI + OPFOLDA

PARTICIPATING SPECIALTY PHARMACIES

Specialty Pharmacy	Contact Information
Accredo Health Group, Inc.	www.accredo.com
CVS Specialty	www.cvsspecialty.com
Orsini Specialty Pharmacy	www.orsinispecialtypharmacy.com

LET AMICUS ASSIST HELP GUIDE THE WAY

AmicusAssist.com

AMICUS ASSIST® is a program that provides dedicated support to individuals who have been prescribed an Amicus medication. We strive to help patients navigate the financial and insurance-related aspects of their treatment while providing personalized assistance every step of the way.

AMICUS ASSIST is ready to help you or your patients.
Call us toll free at 1-833-AMICUS-A (1-833-264-2872), Monday-Friday, 8am-8pm ET.

Hablamos español? Administradores de casos de habla hispaña éstan disponibles.
Llamamos a +1-833-AMICUS-A (+1-833-264-2872) Lunes-Viernes de 8am-8pm ET.

Amicus assist®

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