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

GUIDE TO GETTING STARTED

Treatment Day Checklist and Frequently Asked Questions for Healthcare Providers

Find a treatment day checklist and answers to common questions about the administration of POMBILITI and OPFOLDA, as well as suggestions for other resources with additional information.

INDICATION

POMBILITI in combination with OPFOLDA 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: 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 additional Important Safety Information throughout and on page 10, and full Prescribing Information, including BOXED WARNING, for POMBILITI and full Prescribing Information for OPFOLDA, also available at PombilitiOpfoldaHCP.com.

TREATMENT DAY CHECKLIST

Key Dosing Considerations

- [ ] Confirm appropriate fasting 2 hours prior to the patient taking OPFOLDA[1,2]
- [ ] Check patient weight to confirm sufficient POMBILITI vial supply and OPFOLDA capsule supply[1,2]
- [ ] Inspect each vial carefully and do not use it if the content is discolored, the closure is damaged, and/or the overseal button is missing or has been removed[2]
- [ ] Refer to the Guide to Reconstitution and Administration[2]
- [ ] Visit PombilitiOpfoldaHCP.com for more information about dosing, reconstitution, and administration
- [ ] Review the full Prescribing Information, including BOXED WARNING, for POMBILITI and full Prescribing Information for OPFOLDA

Products

- [ ] **POMBILITI (cipaglucosidase alfa-atga) 105-mg vials** (20 mg/kg actual body weight administered as an infusion every other week)[2]
- [ ] **OPFOLDA (miglustat) 65 mg capsules** (for patients ≥50 kg, 4 capsules [260 mg total] taken orally every other week; ≥40 kg to <50 kg, 3 capsules [195 mg total] taken orally every other week)[1]*
- [ ] Premedications as prescribed

*For recommended dosage in patients with renal impairment, see Section 2.3 of the OPFOLDA full Prescribing Information.

Infusion Supplies & Equipment

- [ ] **Sterile water** for injection at room temperature of 68 °F to 77 °F (20 °C to 25 °C)[2]
- [ ] **Sodium chloride 9 mg/mL (0.9%) solution** for injection at room temperature of 68 °F to 77 °F (20 °C to 25 °C)
  - Choose a bag size based on the patient's body weight[2]
- [ ] **A needle that has a diameter of 18 gauge or less**
  - Do not use filter needles[2]
- [ ] **IV pump, tubing, and filter[2]**
- [ ] **Anaphylaxis kit/supplies** per protocol (ie, epinephrine injection, automated external defibrillator)[2]
- [ ] **Additional supplies** per institution protocol

IMPORTANT SAFETY INFORMATION (continued)

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.

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FREQUENTLY ASKED QUESTIONS

About POMBILITI and OPFOLDA

Q Who is POMBILITI and OPFOLDA appropriate for?

A POMBILITI is a hydrolytic lysosomal glycogen-specific enzyme indicated, in combination with OPFOLDA, an enzyme stabilizer, 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).[1,2]

Q How does POMBILITI work?

A POMBILITI is an enzyme replacement therapy that degrades excess lysosomal glycogen. POMBILITI contains bis-M6P—a type of sugar that can bind to receptors on muscle cells. Bis-M6P allows POMBILITI to be internalized by muscle cells and transported to lysosomes. Once inside the lysosome, POMBILITI undergoes modifications (proteolytic cleavage and N-glycan trimming), and then exerts enzymatic activity in cleaving glycogen.[2]

Q How does OPFOLDA work?

A OPFOLDA binds with, stabilizes, and reduces inactivation of POMBILITI in the blood after infusion. The bound OPFOLDA is dissociated from POMBILITI after it is internalized and transported into lysosomes. OPFOLDA alone has no pharmacological activity in cleaving glycogen.[1]

Q Can a patient switch from another ERT to POMBILITI and OPFOLDA right away?

A A patient can be started on POMBILITI and OPFOLDA at the next scheduled dosing (ie, 2 weeks after the last ERT administration).

Patients should be advised to continue with any premedications used with the previous ERT to minimize infusion-associated reactions (IARs). Depending on tolerability, premedications may be modified. Premedication and/or treatment during infusion with corticosteroids, antihistamines, and antipyretics may be administered to assist with signs and symptoms related to IARs.[1,2]

Q What is the purpose of providing OPFOLDA prior to starting infusion with POMBILITI?

A OPFOLDA should be taken approximately 1 hour prior to POMBILITI so it has time to be absorbed. Given time to absorb, it can then be available to stabilize POMBILITI in the blood during infusion to reduce enzyme inactivation while in circulation.[1,2]

Q Can either medication be provided without the other?

A POMBILITI and OPFOLDA must be taken in combination. Because POMBILITI and OPFOLDA were designed to work exclusively with each other, they must be taken at the right time under the right circumstances. Neither should be taken with another Pompe treatment.[1,2]

IMPORTANT SAFETY INFORMATION (continued)

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.

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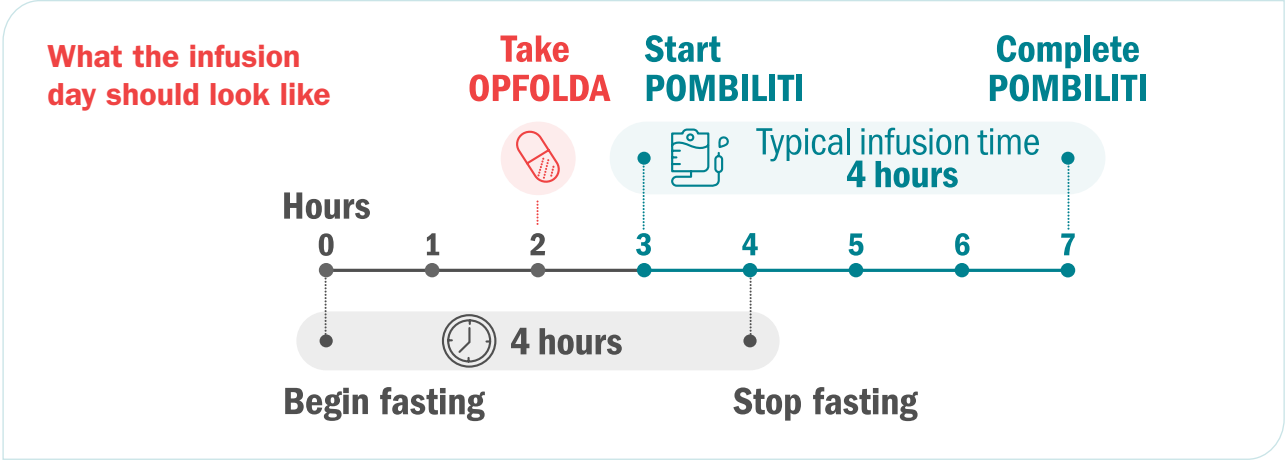
FREQUENTLY ASKED QUESTIONS

Dosing and Administration

Q On average, how long does it take to administer POMBILITI and OPFOLDA?

A The entire process takes about 7 hours, from the beginning of the fast until the end of the infusion. The infusion itself takes about 4 hours. Please see below for a detailed timeline.[1,2]



Q How long should a patient fast prior to taking OPFOLDA?

A Patients are required to fast for 2 hours prior to and 2 hours after taking OPFOLDA. Capsules should be swallowed with unsweetened beverages, including water, tea, and/or coffee with no cream, sugar, or sweeteners. Do not consume other beverages or food during the fasting period. Please refer to the timeline above.[1,2]

Q How do I calculate the number of vials of POMBILITI needed for my patient?

A The formula used for dosing POMBILITI is as follows:

Patient body weight (kg) x 20 mg/kg of actual body weight = Total dose of POMBILITI (mg) administered every other week/105 mg per vial = Number of vials needed[2]

Note: If the number of vials includes a fraction, round up to the next whole number.

Example: 75 mg x 20 mg/kg = 1500 mg/105 mg per vial = 14.29 vials -> 15 vials to reconstitute.[2]

To confirm you've done the calculations correctly, please visit our dosing calculator at PombilitiOpfoldaHCP.com/dosing.

IMPORTANT SAFETY INFORMATION (continued)

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.

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FREQUENTLY ASKED QUESTIONS

Dosing and Administration (continued)

What is the infusion rate for POMBILITI?

The initial recommended infusion rate is 1 mg per kg per hour for the first 30 minutes. Gradually increase the infusion rate by 2 mg/kg/hour every 30 minutes if there are no signs of hypersensitivity or infusion-associated reactions (IARs) until a maximum rate of 7 mg/kg/hour is reached; then, maintain the infusion rate at 7 mg/kg/hour until the infusion is complete. The approximate total infusion duration is 4 hours.

The infusion rate may be slowed or temporarily stopped in the event of mild to moderate IARs. In the event of severe allergic reaction or IAR, immediately stop the infusion, and initiate appropriate medical treatment.[2]

What happens if there is a greater than 3-hour delay in starting POMBILITI after taking OPFOLDA?

If the POMBILITI infusion cannot be started within 3 hours of oral administration of OPFOLDA, reschedule treatment of OPFOLDA and POMBILITI at least 24 hours after OPFOLDA was last taken.[1,2]

How is POMBILITI supplied?

POMBILITI is supplied as a sterile, nonpyrogenic, white to slightly yellowish lyophilized cake or powder for reconstitution with sterile water for injection to yield a concentration of 15 mg/mL, then further diluted with 0.9% sodium chloride for injection for intravenous infusion.

Single-use vials are available in 105-mg dosage only.[2]

How is OPFOLDA supplied?

OPFOLDA capsules are supplied as 65 mg of miglustat, with a grey opaque cap and a white opaque body, printed with “AT2221” in black ink on the body.[1]

What are the key steps to reconstituting POMBILITI?

Use aseptic technique during preparation. Reconstitute and dilute POMBILITI in the following manner[2]:

Reconstitute the Lyophilized Powder

- Determine the number of POMBILITI vials to be reconstituted based on the calculated dose (based on patient’s actual body weight in kg).
- Remove vials from the refrigerator and set aside for approximately 30 minutes to allow vials to come to room temperature.
- Reconstitute each vial by slowly injecting 7.2 mL of Sterile Water for Injection, down the inside wall of each vial to avoid foaming. Avoid forceful impact of Sterile Water for Injection on the lyophilized powder and avoid foaming.
- Roll and tilt each vial to allow the lyophilized powder to dissolve completely which typically takes 2 minutes. Each vial will yield a concentration of 15 mg/mL. Do not invert, swirl, or shake.
- Visually inspect the reconstituted solution for particulate matter and discoloration. The reconstituted solution appears as a clear to opalescent, colorless to yellowish solution essentially particle free. Discard if foreign matter is observed or the solution is discolored.
- Repeat above steps for the number of vials needed for dilution.

Storage of the Reconstituted Solution

- If the reconstituted POMBILITI vials are not used immediately, store refrigerated at 2°C to 8°C (36°F to 46°F) for up to 24 hours. Do not freeze.

IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATION

POMBILITI in combination with OPFOLDA is contraindicated in pregnancy.

Please see additional Important Safety Information throughout and on page 10, and full Prescribing Information, including BOXED WARNING, for POMBILITI and full Prescribing Information for OPFOLDA, also available at PombilitiOpfoldaHCP.com.

Dosing and Administration (continued)

Dilute the Reconstituted Solution

- Remove airspace within a bag of 0.9% Sodium Chloride Injection. Remove an equal volume of 0.9% Sodium Chloride Injection from the bag that will be replaced by the total volume (mL) of reconstituted POMBILITI (see Table 1 of the POMBILITI Prescribing Information for the recommended total infusion volume based on the patient's weight).
- Slowly withdraw 7 mL of reconstituted solution from each of the vials until the patient's dose is obtained. Discard any remaining reconstituted solution in the last vial.
- Add the reconstituted solution slowly and directly into the infusion bag.
- To prevent foaming, gently invert infusion bag to mix the solution and avoid vigorous shaking or agitation. After dilution, the solution will have a final concentration of 0.5 to 4 mg/mL of cipaglucosidase alfa-atga. Do not use a pneumatic tube to transport the infusion bag.
- Administer the diluted solution at room temperature without delay.

Q **Do I need to keep POMBILITI away from sunlight?**

A Yes. Please store in original packaging to protect from light.[2]

Q **Do I need to let POMBILITI come to room temperature prior to reconstitution or infusion?**

A Yes, the infusion should be administered at room temperature. Please remove vials from the refrigerator approximately 30 minutes prior to reconstitution.[2]

Q **How long will a typical infusion last?**

A The typical infusion is administered over approximately 4 hours. The total volume of the infusion is determined by the patient's body weight.[2]

FREQUENTLY ASKED QUESTIONS

Dietary Requirements

Q **What can my patient eat and drink during the fast?**

A During the 4-hour fast, patients can consume unsweetened beverages, including water, tea, and/or coffee with no cream, sugar, or sweeteners.[1]

Q **What can my patient eat and drink during the infusion?**

A Patients can resume normal eating and drinking 2 hours after taking OPFOLDA. Typically this would be about an hour after the infusion starts.[1]

Q **What if a patient does not properly fast prior to taking OPFOLDA?**

A Patients should not take OPFOLDA unless they properly fasted prior to administration.[1]

IMPORTANT SAFETY INFORMATION (continued)

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.

Please see additional Important Safety Information throughout and on page 10, and full Prescribing Information, including BOXED WARNING, for POMBILITI and full Prescribing Information for OPFOLDA, also available at PombilitiOpfoldaHCP.com.

FREQUENTLY ASKED QUESTIONS

Potential Adverse Events

What are the side effects of POMBILITI and OPFOLDA?

Please see full Important Safety Information, including BOXED WARNING, on page 11.

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.[1,2]

In these trials, serious adverse reactions reported in 2 or more patients treated with POMBILITI in combination with OPFOLDA were anaphylaxis and urticaria. A total of 5 patients treated with POMBILITI in combination with OPFOLDA in these trials permanently discontinued POMBILITI due to adverse reactions, including 4 of these patients who discontinued the treatment because of a serious adverse reaction.[1,2]

- Life-threatening hypersensitivity reactions, including anaphylaxis, have been reported in POMBILITI-treated patients. In clinical trials, 41 (27%) POMBILITI-treated patients experienced hypersensitivity reactions, including 4 (3%) patients who reported severe hypersensitivity reactions and 4 (3%) additional patients who experienced anaphylaxis (fulfilling at least one of the Sampson criteria)[2]
- In these trials, infusion-associated reactions were reported in 48 (32%) patients treated with POMBILITI in combination with OPFOLDA[2]

There was no identified clinically significant effect of antidrug antibodies (ADA) on pharmacokinetics or pharmacodynamics of POMBILITI in combination with OPFOLDA over the treatment duration of 52 weeks. Because of the small number of patients with negative ADA, the effect of ADA on the effectiveness of POMBILITI in combination with OPFOLDA is unknown.[2]

Are there any premedications required?

Prior to POMBILITI administration, consider pretreating with antihistamines, antipyretics, and/or corticosteroids. Patients should be advised to continue with any premedications used with the previous ERT to minimize IARs.[2]

Depending on tolerability, premedications may be modified. Please consult the prescribing physician in order to coordinate appropriate premedications.

IMPORTANT SAFETY INFORMATION (continued)

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.

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FREQUENTLY ASKED QUESTIONS

Potential Adverse Events (continued)

Q **Are there any considerations when providing this medication to elderly patients?**

A Clinical trials of OPFOLDA in combination with POMBILITI did not include sufficient numbers of patients 65 years of age and older to determine whether they respond differently from younger adult patients.[1,2]

Q **Can POMBILITI and OPFOLDA be used during pregnancy?**

A POMBILITI in combination with OPFOLDA is contraindicated in pregnancy. 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 of females of reproductive potential prior to initiating 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.[1,2]

Infusion-Associated Reactions

Q **What do I do in the event of an infusion-associated reaction?**

A If severe infusion-associated reactions occur, immediately discontinue the POMBILITI infusion, initiate appropriate medical treatment, and assess the benefits and risks of readministering POMBILITI following severe IARs. Patients may be rechallenged using slower infusion rates. Once a patient tolerates the infusion, the infusion rate may be increased to reach the recommended infusion rate. If mild or moderate IARs occur regardless of pretreatment, decreasing the infusion rate or temporarily stopping the infusion may ameliorate the symptoms.[2]

Q **What do I do in the event of a hypersensitivity reaction including anaphylaxis?**

A If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, POMBILITI should be discontinued immediately, and appropriate medical treatment should be initiated. The risks and benefits of readministering POMBILITI following severe hypersensitivity reaction (including anaphylaxis) should be considered. Patients may be rechallenged using slower infusion rates. In patients with severe hypersensitivity reaction, desensitization measures to POMBILITI may be considered. If the decision is made to readminister POMBILITI, ensure the patient tolerates the infusion. If the patient tolerates the infusion, the dosage (dose and/or the rate) may be increased to reach the approved recommended dosage. If a mild or moderate hypersensitivity reaction occurs, the infusion rate may be slowed or temporarily stopped.[2]

IMPORTANT SAFETY INFORMATION (continued)

LACTATION

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

Please see additional Important Safety Information throughout and on page 10, and full Prescribing Information, including BOXED WARNING, for POMBILITI and full Prescribing Information for OPFOLDA, also available at PombilitiOpfoldaHCP.com.

STORAGE

How to Store POMBILITI[1,2]

POMBILITI is supplied as a sterile, nonpyrogenic, white to slightly yellowish lyophilized cake or powder for reconstitution with sterile water for injection to yield a concentration of 15 mg/mL; then further diluted with 0.9% sodium chloride for injection for intravenous infusion. Single use vials are available in 105-mg dosage only.

- Store at 36 °F to 46 °F
- Do not freeze
- Store in the original packaging to protect from light

Storage for reconstituted and diluted solution

- Do not freeze the reconstituted vial or the diluted POMBILITI solution in the infusion bag for infusion

Infusion Preparation	Infusion-use Stability	
	Refrigerated Storage 36 °F to 46 °F (2 °C to 8 °C)	**Room Temperature Storage** 68 °F to 77 °F (20 °C to 25 °C)
Once POMBILITI vial is reconstituted with sterile water for injection	**24 hours**	**Not recommended**
Once reconstituted vial is diluted with sodium chloride 9 mg/mL (0.9%) solution for injection in the infusion bag	**16 hours***	**Not recommended**

*After removal of the diluted solution from the refrigerator:
- Completely infuse within 6 hours.
- Do not restore in the refrigerator.

How to Store OPFOLDA[1]

- OPFOLDA is supplied as a hard gelatin capsule containing 65 mg of miglustat
- Store at 68 °F to 77 °F (20 °C to 25 °C). Excursions are permitted between 59 °F to 86 °F (15 °C to 30 °C)
- Do not use if inner seal is missing or broken
- Keep out of reach of children
- Store in the original container or equivalent to protect from light

IMPORTANT SAFETY INFORMATION (continued)

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.

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IMPORTANT SAFETY INFORMATION

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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.

CONTRAINDICATION

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LACTATION

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INDICATION

POMBILITI in combination with OPFOLDA 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).

Please see full Prescribing Information, including BOXED WARNING, for POMBILITI and full Prescribing Information for OPFOLDA, and also available at PombilitiOpfoldaHCP.com.

REFERENCES

1. OPFOLDA. Prescribing information. Amicus Therapeutics US, LLC; 2024. **2.** POMBILITI. Prescribing information. Amicus Therapeutics US, LLC; 2024.

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

ADDITIONAL INFORMATION

About POMBILITI AND OPFOLDA

If you have additional questions, contact your Amicus Rare Disease Specialist: PombilitiOpfoldaHCP.com/Request-A-Rep

To speak with a Patient Education Liaison, contact: 1-833-AMICUS-A (1-833-264-2872), Monday through Friday, 8AM to 8PM ET

For more, go to: PombilitiOpfoldaHCP.com

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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.

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