

ZAVESCA® (miglustat) Physician Statement

accredo®



First Name: _____ Last Name: _____

Medical Degree: _____ Specialty: _____

Organization/Institution/Clinic Name: _____

Street Address: _____

City: _____ State: _____ ZIP Code: _____

Office Phone: _____ Fax: _____

Email Address: _____

DEA No: _____ State License No: _____

I understand that the US Food and Drug Administration (FDA) requires that prescriptions for ZAVESCA® (miglustat) capsules be filled only on order of a physician who affirms that he or she is knowledgeable in the management of the disease for which ZAVESCA is indicated. I have studied and familiarized myself with the ZAVESCA package insert, the safety and efficacy profile of ZAVESCA, and required testing.

Adverse Event Reporting

I understand that it is important for me to report any adverse events my ZAVESCA patients may experience. I will report suspected adverse reactions by contacting Actelion at 1-866-ACTELION (1-866-228-3546), or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

I affirm that I have read the preceding paragraphs and meet the criteria stated in them.

Please fax this signed form (within 48 hours) to an Accredo representative at 1-877-773-9233.

For additional information or to speak with an Accredo representative, call 1-877-472-1326.

Signature: _____ Date: _____

Please Print Name: _____

ZAVESCA is a glucosylceramide synthase inhibitor indicated as monotherapy for the treatment of adult patients with mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option (e.g. due to allergy, hypersensitivity, or poor venous access).

The most common serious adverse reaction reported with ZAVESCA treatment in clinical trials was peripheral neuropathy. The most common adverse reactions requiring intervention were diarrhea and tremor. Patients should undergo neurological examination at the start of treatment and every 6 months thereafter; ZAVESCA should be reassessed in patients who develop symptoms of peripheral neuropathy. ZAVESCA is Pregnancy Category C and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Please see accompanying full Prescribing Information.

Actelion Pharmaceuticals US, Inc.

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