Reference ID: 4639802

myalept (metreleptin) for injection

MYALEPT® REMS Program

A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure that the benefits of a drug outweigh its risks.

The MYALEPT REMS Program was developed with the FDA:

To educate prescribers about
- the development of anti-metreleptin antibodies that neutralize endogenous leptin and/or MYALEPT and the serious adverse events that may result from these antibodies,
- the risk of lymphoma, and
- appropriate patient selection

Program Requirements

MYALEPT is available only through the MYALEPT REMS Program. The MYALEPT REMS Program requirements include:

For Prescribers:

- **Certification** of prescribers of MYALEPT
  - Certification consists of completion of **training, and enrollment** in the MYALEPT REMS Program
- **Completion** of a Prescription Authorization form for **each** new prescription

Find out more about Training & Enrollment

For Pharmacies:

- **Restricted distribution** of MYALEPT to patients with completed Prescription Authorization Forms from prescribers who are certified in the MYALEPT REMS Program

Training & Enrollment

Healthcare providers who prescribe MYALEPT must review the prescriber training materials to enroll in the MYALEPT REMS Program.

Steps to Prescriber Certification

1. **Review the Prescriber Education Materials**
   - MYALEPT Prescribing Information
   - Prescriber Training Module
2. **Complete and submit the MYALEPT REMS Program Prescriber Enrollment Form**
   - Print and sign the Prescriber Enrollment Form or request a copy by calling 1-855-669-2537
   - Submit the form via Fax to 1-877-328-9682

By completing the Prescriber Enrollment Form, the prescriber agrees to comply with the MYALEPT REMS Program requirements. A confirmation of your certification in the MYALEPT REMS program will be sent to you so you can begin to prescribe MYALEPT.

Reporting Adverse Reactions

Healthcare providers should report all suspected adverse events.
Please contact the company at **1-855-669-2537** or FDA at **1-800-FDA-1088** or www.fda.gov/medwatch.com.

REMS Materials

- PDF MYALEPT REMS Program: An Introduction
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- PDF Prescribing Information
- PDF Myalept REMS Letter for HCPs (Infections)

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Hours of Operation:
Monday - Friday,
8:00am-8:00pm
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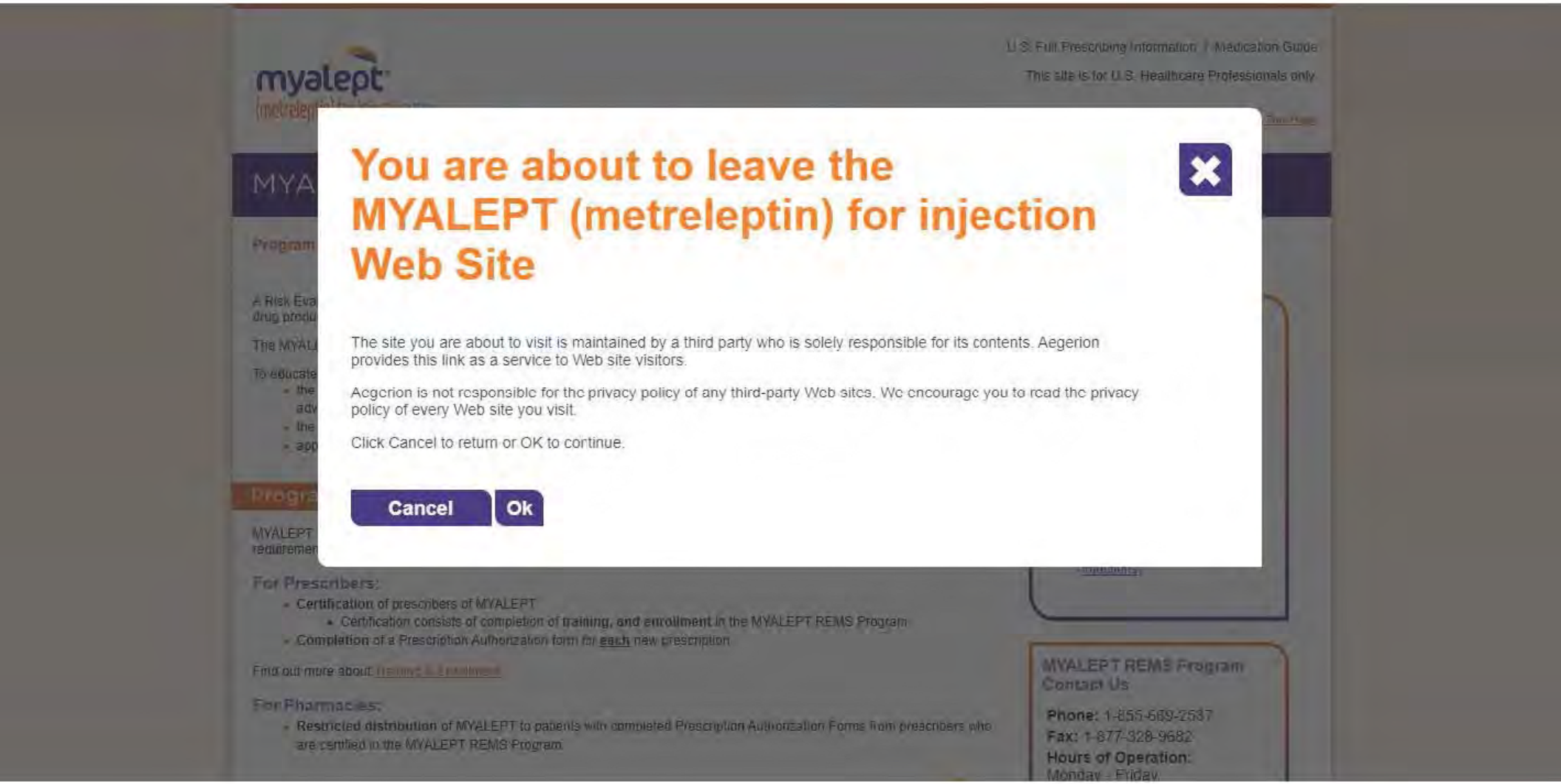

MYALEPT® REMS Program

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MYALEPT® REMS Program

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APPENDIX 5
MYALEPT REMS PRESCRIPTION AUTHORIZATION FORM