

INSTRUCTIONS

Clozapine is only available through the Clozapine Risk Evaluation and Mitigation Strategy (REMS). This form must be completed and returned to the Clozapine REMS before clozapine products may be shipped to certified pharmacies. This form applies to all wholesaler-distributors who wish to purchase any clozapine product.

In order to distribute clozapine, the wholesaler-distributor must designate an authorized representative to carry out the registration process and oversee implementation and compliance with the Clozapine REMS on behalf of the wholesaler-distributor.

The authorized representative for the wholesaler-distributor must:

- Review and agree to the responsibilities below.
- Complete and submit this Clozapine REMS Wholesaler-Distributor Registration Form.

Please complete the requested information below and fax to 800-878-5927. If you have any questions, require additional information, or need copies of Clozapine REMS documents, please visit the Clozapine REMS Website at www.clozapinerems.com, or call the Clozapine REMS Contact Center at 888-586-0758.

WHOLESALER-DISTRIBUTOR INFORMATION (All fields are required, unless otherwise noted)

Wholesaler-Distributor Name:

Address:

City:

State:

Zip Code:

Phone:

Fax:

Wholesaler-Distributor DEA # (required if registering a single location):

AUTHORIZED REPRESENTATIVE INFORMATION (All fields are required)

First Name:

Last Name:

Phone:

Fax:

Email Address:

Preferred Method of Contact (please select one): Email Fax Phone Call

Continued on the next page

AUTHORIZED REPRESENTATIVE AGREEMENT

I am the Authorized Representative designated by my wholesaler-distributor to carry out the registration process and oversee implementation and compliance with the Clozapine REMS on behalf of the wholesaler-distributor. As the Authorized Representative, I understand that wholesalers-distributors that distribute clozapine must:

To be able to distribute clozapine:

- Establish processes and procedures to ensure that clozapine is distributed only to certified pharmacies
- Train all relevant staff involved in distribution on the requirement of the Clozapine REMS

At all times:

- Distribute only to certified pharmacies or a registered wholesaler-distributor
- Maintain records of monthly drug distribution for all clozapine shipments and provide the data upon request of manufacturer(s) or a third party acting on behalf of the manufacturer(s)
- Comply with audits carried out by the manufacturers or a third party acting on behalf of the manufacturers, to ensure that all processes and procedures are in place and are being followed

Authorized Representative Signature:**Date (MM/DD/YYYY):**

Continued on the next page

AUTHORIZED REPRESENTATIVE AGREEMENT

I am the Authorized Representative designated by my wholesaler-distributor to carry out the registration process and oversee implementation and compliance with the Clozapine REMS on behalf of the wholesaler-distributor. As the Authorized Representative, I understand that wholesalers-distributors that distribute clozapine must:

To be able to distribute clozapine:

- Establish processes and procedures to ensure that clozapine is distributed only to certified pharmacies
- Train all relevant staff involved in distribution on the requirement of the Clozapine REMS

At all times:

- Distribute only to certified pharmacies or a registered wholesaler-distributor
- Maintain records of monthly drug distribution for all clozapine shipments and provide the data upon request of manufacturer(s) or a third party acting on behalf of the manufacturer(s)
- Comply with audits carried out by the manufacturers or a third party acting on behalf of the manufacturers, to ensure that all processes and procedures are in place and are being followed

Authorized Representative Signature:**Date (MM/DD/YYYY):**

Continued on the next page