



Caraco Clozapine Distribution System (CCDS) FORM A: TEAM REGISTRATION

Internal Use
TEAM Code

Doctor and Pharmacist: This Form is for registering Physician and Pharmacist as a TEAM with CCDS.

Fields marked with * are required for processing

Responsibilities of the Physician and Pharmacist

1. We have reviewed and understand the Clozapine package insert.
2. All dispensing Pharmacists in my Pharmacy have reviewed the package insert and understand the same.
3. We are aware of the risks involved with Clozapine therapy and understand that death could occur as a result of agranulocytosis and myocarditis.
4. We understand that Clozapine has been associated with agranulocytosis, which can be fatal. All patients on Caraco's Clozapine should be enrolled into Caraco's CCDS system to help reduce the risk of rechallenge in a patient with prior unacceptable WBC counts (Total WBC count less than 3500/mm³ & ANC less than 2000 mm³).
5. We understand that Clozaril is not approved for patients with dementia-related psychosis. Patients with prior history of Myoproliferative disorders or previous Clozapine induced Granulocytosis or Agranulocytosis will not be included in Caraco's CCDS.
6. We understand that the patient's status will be verified with Clozaril® National Registry prior to assignment of a Patient Code for patients new to treatment or with an unknown history.
7. I the Physician will prescribe Caraco's Clozapine only following the receipt of a Patient Code from the Caraco's CCDS Registry.
8. I the Physician agree to closely monitor the WBC counts of the patients and report them to CCDS or the Pharmacist for their submission to CCDS within 7 days of the blood draw date for patients monitored weekly, within 14 days for patients monitored bi-weekly, or 28 days for patients monitored monthly.
9. I the Pharmacist also understand that Clozapine cannot be given to a new patient prior to registration and that this option is not available to new patients. I understand that 1 week's supply of Clozapine can be given to a patient already undergoing Clozapine therapy prior to TEAM and patient registration. I hereby commit to completing the registration requirements prior to the next weeks supply of Caraco Clozapine.
10. I the Pharmacist, agree to submit to CCDS the WBC reports within 7 days of the blood draw date for patients monitored weekly, within 14 days for patients monitored bi-weekly, or 28 days for patients monitored monthly.
11. We agree to report any abnormalities and any discontinuations to Caraco's CCDS and submit the blood counts weekly upto 4 weeks after discontinuation of Clozapine therapy as per CCDS protocol.
12. We understand that the Caraco's CCDS patient Registry will monitor compliance with reporting requirements and will notify the physician and/or pharmacist of the patient's Treatment Team of any discrepancies or overdue lab reports.
13. I understand that CCDS may need to contact the physician and/or the pharmacist to resolve discrepancies.

Completion and signing of this form demonstrates my intention to participate in the CCDS and constitutes my commitment to dispensing of Clozapine upon receipt of acceptable WBC and differential counts in compliance with CCDS. We understand that CCDS reserves the right to withdraw the prescribing and dispensing privileges based upon compliance issues including, but not limited to those previously identified.

*Signature of Pharmacist _____

Date (mm/dd/yy) _____

*Signature of Physician _____

Date (mm/dd/yy) _____

PHARMACIST

***Please place an "X" in the appropriate box:**

1. I am currently enrolled in another manufacturer's Clozapine Distribution system. Yes No
2. I am currently dispensing Clozaril® (or another Clozapine). Yes No

(If registered with CCDS, only stocking Code required)

Pharmacy Stocking Code _____

*Pharmacy Name _____

*PharmacyDEA/ID#

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*Name _____

Last First Middle

Title _____

*Pharmacy Address: _____

*City _____ *State _____ *ZIP code _____

*Tel: (_____) _____

*Fax: (_____) _____

E-mail Id: _____

*Wholesaler Name/Division _____

*Address: _____

*City _____ *State _____ *ZIP code _____

*Tel: (_____) _____

*Fax (_____) _____

PHYSICIAN

(If registered with CCDS, only DEA/ID # required)

*Name _____

Last First Middle

*Physician DEA/ID #

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*Address: _____

*City _____ *State _____ *ZIP code _____

*Tel: (_____) _____

* Fax (_____) _____

Associated Institution / Hospital: _____

**Mail Form to: CCDS, Caraco Pharmaceutical Laboratories Ltd.,
1150 Elijah McCoy Drive, Detroit, MI 48202.**
Toll Free Fax: 1-800-980-CCDS (2237)
Toll Free Tel: 1-888-Tel-CCDS (835-2237)
Website : www.caracoclozapine.com

On issuing the TEAM registration and the Pharmacy Stocking Code, appropriate members of the distribution channel will be informed about the Pharmacy's CCDS registration for purchase of Caraco's Clozapine