



**STATUS DECISION OF CONTROLLED AND NON-CONTROLLED SUBSTANCE(S)**

Substance: Norclozapine

Based on the current information available to the Office of Controlled Substances, it appears that the above substance is:

Controlled  X  
Not Controlled

under the schedules of the *Controlled Drugs and Substances Act* (CDSA) for the following reason(s):

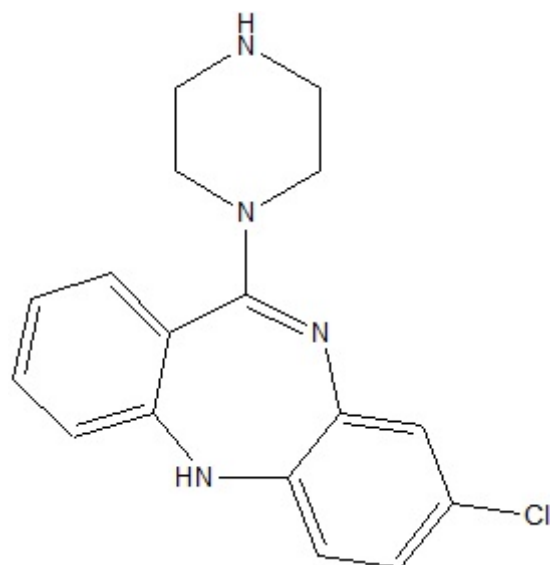
- Item 18 of Schedule IV to the CDSA is, “Benzodiazepines, their salts and derivatives, including: ...”
- The benzodiazepines have a characteristic structural feature and clozapine is considered to be included in the class, benzodiazepines, due to its chemical structure.
- A regulatory decision was made that clozapine did not need to be subject to the control mechanisms, etc. which apply generally to benzodiazepine. Therefore it was excepted from the class by listing the substance in the “but not including” portion of item 18.
- Structurally, norclozapine is a benzodiazepine.

Supporting document(s) attached:  X

Prepared by: TIANA BRANCH Date: 2005-06-28

Verified by: See e-mail MIKE LABELLE Date: 2005-06-28

Approved by: \_\_\_\_\_ Date: \_\_\_\_\_  
DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES



Norclozapine

**Related Names**

8-Chloro-11-(1-piperazinyl)-5H-dibenzo(b,e)(1,4)diazepine

N-Desmethylozapine

5H-Dibenzo(b,e)(1,4)diazepine, 8-chloro-11-(1-piperazinyl)-

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**Drug Status Report**

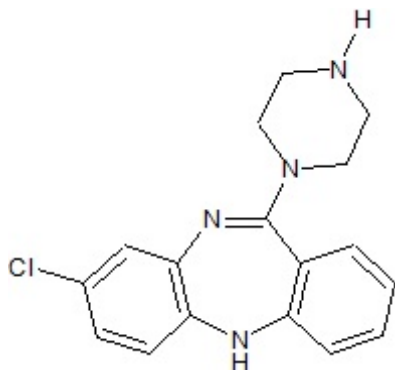
**Drug:** Norclozapine

**Drug Name Status:** Norclozapine is the common name

**Chemical Name:** 8-chloro-11-(1-piperazinyl)-5H-dibenzo[b,e][1,4]diazepine

**Other Names:** N-desmethylozapine

**Chemical structure:**



**Molecular Formula:** C<sub>17</sub>H<sub>17</sub>ClN<sub>4</sub>

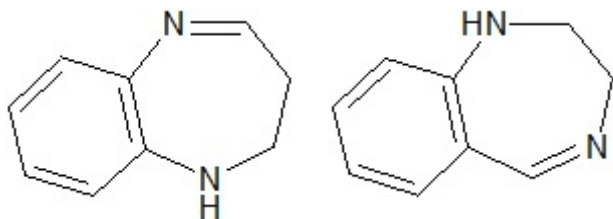
**Pharmacological class / Application:** benzodiazepine

**International status:**

US: The drug is not currently listed on the US Controlled Substances Act and is not mentioned on the DEA website.

United Nations: The drug is not listed on the Yellow List - List of Narcotic Drugs under International Control. The drug is not listed on the Green List - List of Psychotropic Substances under International Control. The latter list includes several benzodiazepines but they are listed individually and clozapine and norclozapine are not listed substances.

Canadian Status: Item 18 of Schedule IV to the CDSA is, "Benzodiazepines, their salts and derivatives, including:" The benzodiazepines have a characteristic structural feature and clozapine is considered to be included in the class, benzodiazepines, due to its chemical structure. Two variations of the characteristic feature are shown on the next page. A regulatory decision was made that clozapine did not need to be subject to the control mechanisms, etc. which apply generally to benzodiazepine. Therefore it was excepted from the class by listing the substance in the "but not including" portion of item 18.



Structurally, norclozapine is a benzodiazepine.

Recommendation: Norclozapine is a benzodiazepine which is a group of substances listed in item 18 of Schedule IV to the CDSA and is a controlled substance.

June 28, 2005