



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

Substance: Bisnortilidine

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

Controlled [checked]
Not Controlled [unchecked]

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

- The substance is a metabolite of tilidine and therefore included under item 17 of Schedule I to the CDSA.

Prepared by: Evelyn Soo Date: Nov 26th 2010

Verified by: Marianne Tang Date:

Approved by: DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES Date:

This status was requested by: third party information removed as per agreement with applicant

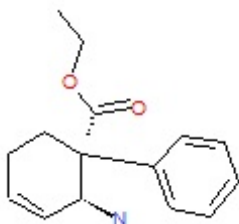
Drug Status Report

Drug: Bisnortilidine

Drug Name Status: Bisnortilidine is the common name.

Chemical Name: Trans-(±)-2-amino-1-phenyl-3-cyclohexene-1-carboxylic acid, ethyl ester

Chemical structure:



Molecular Formula: C₁₅H₁₉NO₂

Pharmacological class /Application: Metabolite of tilidine

CAS-RN: 53948-51-9

International status:

US: Bisnortilidine is not currently listed in the schedules to US Controlled Substances Act nor mentioned anywhere on the DEA website.

United Nations: The substance is not listed on the Yellow List - List of Narcotic Drugs under International Control nor the Green List - List of Psychotropic Substances under International Control.

Canadian Status: Bisnortilidine is not listed specifically in the CDSA. However, the substance is a metabolite of tilidine¹ and therefore is captured under the heading “Tilidine (ethyl-2-(dimethylamino)-1-phenyl-3-cyclohexene-1-carboxylate), its salts, derivatives and salts of derivatives” of item 17 of Schedule I to the CDSA as a derivative of tilidine.

Recommendation: Bisnortilidine is included under item 17 of Schedule I to the CDSA and is a controlled substance.

Date: 26 November 2010

¹Hengy, H. *et al.* (1978) GLC determination of tilidine, nortilidine, and bisnortilidine in biological fluids with a nitrogen-sensitive detector, *J. Pharm. Sci.* **67**:1765-1768.