



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

Substance: Ranolazine

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

Controlled []
Not Controlled [x]

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

- The substances are not anabolic steroids nor derivatives of anabolic steroids.

Prepared by: Evelyn C Soo Date: Nov 19th 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".

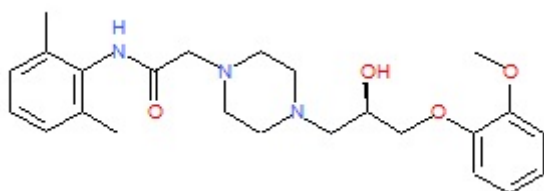
Drug Status Report

Drug: Ranolazine

Drug Name Status: Ranolazine is the common name.

Chemical Name: N-(2,6-dimethylphenyl)-4-(2-hydroxy-3)-(2-methoxyphenoxy)propyl)-1-piperazineacetamide

Chemical structure:



Molecular Formula: $C_{24}H_{33}N_3O_4$

Pharmacological class / Application: Anti-ischemic

CAS-RN: 95635-55-5

International status:

US: The substance is not listed specifically in the CSA and is not 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: Ranolazine is an anti-anginal and anti-ischemic drug used for the treatment of angina¹ and is not currently listed in the CDSA. The substance is also not similar in structure to any of the substances included in the Schedules to the CDSA.^{2,3}

¹Stone, PH et al. (2010) The anti-ischemic mechanism of action of ranolazine in stable ischemic heart disease, *J. Am. Coll. Cardiol.* **56**:934-342..

²Zhou, F. et al. (2010) Continuous administration of low-dose cyclophosphamide and prednisone as a salvage treatment for multiple myeloma, *Clin. Lymphoma, Myeloma, Leukemia*, **10**:51-55.

³De LT Vieira et al. (2010) Simultaneous HPLC analysis of triamcinolone acetonide and budesonide in microdialysate and rat plasma: application of a pharmacokinetic study, *J. Chromatogr. B.* **878**:2967-2973.

Recommendation: Ranolazine is not included in the schedules to the CDSA and is not a controlled substance.

Date: November 19th 2010