



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

Substance: I - Prednisone
II - Fluoxyprednisone

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

Controlled
Not Controlled

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".

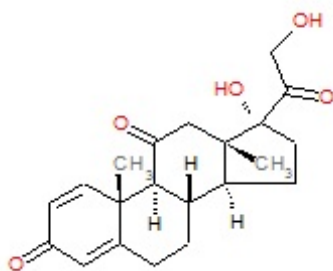
Drug Status Report

Drug: I - Prednisone
II - Triamcinolone

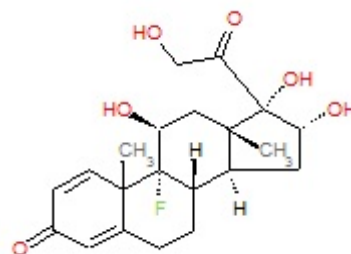
Drug Name Status: I - Prednisone
II - Triamcinolone are the proper (INN) names.

Chemical Name: I - 17,21-Dihydroxy-pregna-1,4-diene-3,11-20-trione
II - 9-Fluoro-11,16,17,21-pregan-1,4-diene-3,20-dione

Chemical structure:



I



II

Molecular Formula: I - $C_{21}H_{26}O_5$; I - $C_{21}H_{27}FO_6$

Pharmacological class / Application: Steroid

CAS-RN: I - 53-03-2; II - 124-94-7

International status:

US: The substances are not listed specifically in the CSA and are not mentioned anywhere on the DEA website.

United Nations: The substances are 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: Prednisone and triamcinolone are synthetic corticosteroids which display immunosuppressant and anti-inflammatory activities and are used for the treatment of a range

of inflammatory diseases including rheumatoid arthritis, eczema and even some cancers^{1,2,3}. The substances have not been reported in the scientific literature to display any anabolic activity and are not derived from an anabolic steroid. Accordingly, prednisone and triamcinolone are not included under the heading “Anabolic steroids and their derivatives including” of item 23 of Schedule IV to the CDSA.

Recommendation: Prednisone and triamcinolone are not included in the schedules to the CDSA and are not a controlled substances.

Date: November 19th 2010

¹Cutolo, M. et al. (2010) Inflammatory gene profile in early rheumatoid arthritis and modulation by leflunomide and prednisone treatment, *Ann. New York Acad.Sci.* **1193**:15-21.

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) Simulatneous HPLC analysis of triamcinolone acetonide and budesonide in microdialysate and rat plasma: application of a pharmacokinetic study, *J. Chromatogr. B.* **878**:2967-2973.