Health Canada Santé Canada

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

Substance: Bromfenac sodium

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 substance is not similar in structure to any of those listed in the CDSA.

Prepared by: _____ Date: February 7th, 2012
Vincent Marleau

Verified by: _____ Date: _____
Mark Kozlowski

Approved by: _____ Date: _____
DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

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

Drug Status Report

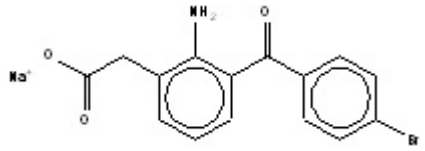
Drug: Bromfenac sodium

Drug Name Status: Bromfenac sodium is the common name.

Chemical Name: 2-Amino-3-(4-bromobenzoyl)-benzeneacetic acid, , monosodium salt, sesquihydrate

Other names: Bromfenac ophthalmic; Duract; Sodium 2-amino-3-(4-bromobenzoyl) phenylacetate sesquihydrate; Benzeneacetic acid, 2-amino-3-(4-bromobenzoyl)-, monosodium salt, hydrate (2:3).

Chemical structure:



Molecular Formula: $C_{15}H_{12}BrNO_3.3/2\ H_2O.Na$

Pharmacological class / Application: NSAID

CAS-RN: 120638-55-3

International status:

US: Bromfenac sodium is not listed in the schedules to the *US Controlled Substances Act* 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, the Green List - List of Psychotropic Substances under International Control, nor the Red List - List of Precursors and Chemicals Frequently Used in the Illicit Manufacture of Narcotic Drugs and Psychotropic Substances Under International Control.

Canadian Status: Bromfenac sodium is not listed in the schedules to the CDSA. The substance is a non-steroidal anti-inflammatory drug which is generally used as an ophthalmic analgesic[1] but has also been reported to be useful for the treatment of pain after surgical procedures such as oral surgery[2]. Bromfenac sodium is not similar in structure to any of the substances listed in the

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[1]Waterbury, LD et al. (2006) Comparison of cyclooxygenase inhibitory activity and ocular anti-inflammatory effects of ketorolac tromethamine and bromfenac sodium. Curr. Med. Res. Opin. **22**:1133-1140.

[2]Hersh, EV et al. (1998) A dose-ranging study of bromfenac sodium in oral surgery pain. Oral Surgery, Oral Med., Oral Pathol. Oral Radiol. Endodontics, **86**:36-41.

schedules to the CDSA.

Recommendation: Bromfenac sodium is not included in any of the Schedules to the CDSA and is not a controlled substance.

Date: February 7th, 2012.