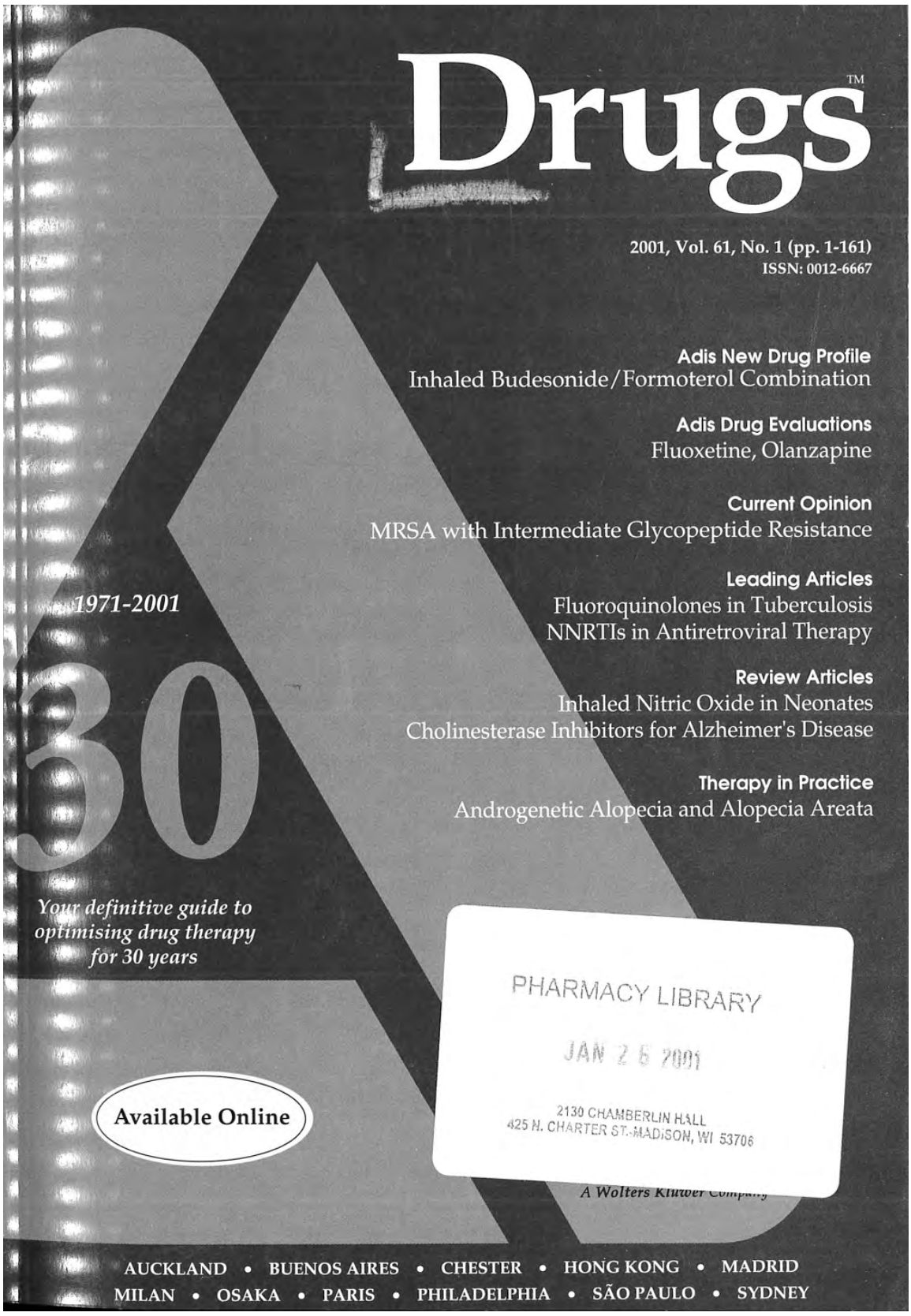

Roxane Labs., Inc.
Exhibit 1013
Page 001

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

Find authenticated court documents without watermarks at docketalarm.com.

adis INTERNATIONAL
A Wolters Kluwer Company

Drugs™

International Editorial Board

D.R. Abernethy, *Baltimore, MD, USA*
S. Bank, *New York, NY, USA*
P.J. Barnes, *London, England*
P.N. Bennett, *Bath, England*
W.M. Bennett, *Portland, OR, USA*
G. Bianchi Porro, *Milan, Italy*
W.R. Bowie, *Vancouver, BC, Canada*
A.M. Breckenridge, *Liverpool, England*
D.B Calne, *Vancouver, BC, Canada*
L. de Angelis, *Trieste, Italy*
F.T. Fraunfelder, *Portland, OR, USA*
E.D. Freis, *Washington, DC, USA*
W.H. Frishman, *Valhalla, NY, USA*
B.G. Gazzard, *London, England*
D.C. Harrison, *Cincinnati, OH, USA*
F.D. Hart, *London, England*
E.C. Huskisson, *London, England*
T. Itoh, *Osaka, Japan*
D. Jewitt, *London, England*
G.D. Johnston, *Belfast, N. Ireland*
M.H. Lader, *London, England*
M.J.S. Langman, *Birmingham, England*
H. Lode, *Berlin, Germany*
H.I. Malbach, *San Francisco, CA, USA*
F.H. McDowell, *White Plains, NY, USA*
F.M. Muggia, *New York, NY, USA*
K.G. Naber, *Straubing, Germany*
S. Nattel, *Montreal, PQ, Canada*
C.E. Nord, *Huddinge, Sweden*
H. Pardell, *Barcelona, Spain*
P. Patsalos, *London, England*
R. Pauwels, *Ghent, Belgium*
J.C. Petrie, *Aberdeen, Scotland*
B.N.C. Prichard, *London, England*
S.H. Roth, *Phoenix, AZ, USA*
S. Shuster, *Framlingham, England*
B.N. Singh, *Los Angeles, CA, USA*
T.M. Speight, *Auckland, New Zealand*
J.S. Turner, *Gainesville, GA, USA*
J. Turnidge, *Adelaide, SA, Australia*
J.A. Vale, *Birmingham, England*
D.J. Zegarelli, *New York, NY, USA*

Aim and Scope: *Drugs* promotes optimum pharmacotherapy by providing a programme of review articles covering the most important aspects of clinical pharmacology and therapeutics.
The Journal includes:

- Leading/current opinion articles providing an overview of contentious or emerging issues
- Definitive reviews of drugs and drug classes and their place in disease management
- Therapy in Practice articles including recommendations for specific clinical situations
- Adis Drug Evaluations reviewing the properties and place in therapy of both newer and established drugs
- Adis New Drug Profiles with expert commentary.

All manuscripts are subject to peer review by international experts. Letters to the editor are welcomed and will be considered for publication.

Editor: Dene C. Peters

Publication Manager: Kim Slattery

Editorial Office and Inquiries: Adis International Ltd, 41 Centorian Drive, Private Bag 65901, Mairangi Bay, Auckland 10, New Zealand. Information on the preparation of manuscripts will be provided to authors.

E-mail: drugs@adis.co.nz http://www.adis.com

Drugs (ISSN 0012-6667) is published by Adis International Limited, 41 Centorian Drive, Private Bag 65901, Mairangi Bay, Auckland 10, New Zealand. Annual 2001 subscription price: $US1995; Japan ¥332 478. Annual subscription consists of 15 issues. (Further subscription information is given at the back of each issue.)

Policy Statement: Although great care has been taken in compiling the content of this publication, the publisher and its servants are not responsible or in any way liable for the currency of the information, for any errors, omissions or inaccuracies, or for any consequences arising therefrom. Inclusion or exclusion of any product does not imply its use is either advocated or rejected. Use of trade names is for product identification only and does not imply endorsement. Opinions expressed do not necessarily reflect the views of the Publisher, Editor or Editorial Board.

Copyright: © 2001 Adis International Ltd. All rights reserved throughout the world and in all languages. No part of this publication may be reproduced, transmitted or stored in any form or by any means either mechanical or electronic, including photocopying, recording, or through an information storage and retrieval system, without the written permission of the copyright holder.
The appearance of the code at the top of the first page of an article in this journal indicates the copyright owner's consent that copies of the article may be made for the personal or internal use of specific clients. This consent is given provided that the fee of $US27.50 per copy is paid directly to the Copyright Clearance Center Inc., 222 Rosewood Drive, Danvers, Massachusetts 01923, USA, for copying beyond that permitted by sections 107 or 108 of the US Copyright Law. This consent does not extend to other kinds of copying such as copying for general distribution, for advertising or promotional purposes, for creating new collective works, or for resale.

Roxane Labs., Inc.
Exhibit 1013
Page 002

Vol. 61, No. 1, 2001

Drugs™

Contents

PHARMACY LIBRARY

JAN 2 6 2001

2130 CHAMBERLIN HALL
425 N. CHARTER ST. MADISON, WI 53706

Drugs is indexed in *Index Medicus, Medline, EMBASE/Excerpta Medica, Current Contents/Clinical Medicine, Current Contents/Life Sciences, BIOSIS® Database, International Pharmaceutical Abstracts (IPA)* and *CABS*. Individual articles are available through the ADONIS document delivery service and on-line via the World Wide Web through Ingenta. Further details are available from the publisher.

Roxane Labs., Inc.
Exhibit 1013
Page 003

DOCKET ALARM

Find authenticated court documents without watermarks at docketalarm.com.

This material may be protected by Copyright law (Title 17 U.S. Code)

ADIS DRUG EVALUATION

Drugs 2001; 61 (1): 81-110
0012-6667/01/0001-0081/$27.50/0

© Adis International Limited. All rights reserved.

Fluoxetine

A Review of its Therapeutic Potential in the Treatment of Depression Associated with Physical Illness

Susan M. Cheer and *Karen L. Goa*

Adis International Limited, Auckland, New Zealand

Various sections of the manuscript reviewed by:
M. Ansseau, Psychiatric Unit, Liege, Belgium; ***M. Isaac***, Psychopharmacology Evaluation Unit, University Hospital, London, England; ***M. Lader***, Institute of Psychiatry, London, England; ***S.H. Preskorn***, Psychiatry Department, University of Kansas School of Medicine, Wichita, Kansas, USA; ***J.G. Rabkin***, Department of Psychiatry, College of Physicians and Surgeons, Columbia University, New York, New York, USA.

Data Selection
Sources: Medical literature published in any language since 1966 on Fluoxetine, identified using Medline and EMBASE, supplemented by AdisBase (a proprietary database of Adis International, Auckland, New Zealand). Additional references were identified from the reference lists of published articles. Bibliographical information, including contributory unpublished data, was also requested from the company developing the drug.
Search strategy: Medline search terms were 'Fluoxetine' or 'LY 110140' and ('cardiovascular-diseases' or 'neoplasms' or 'HIV' or 'acquired-immunodeficiency-syndrome' or 'diabetes-mellitus' or 'hypotension-orthostatic'). EMBASE search terms were 'Fluoxetine' or 'LY 110140' and ('stroke' or 'cardiovascular-disease' or 'cancer' or 'human-immunodeficiency-virus' or 'acquired-immune-deficiency-syndrome' or 'diabetes-mellitus' or 'heart-infarction' or 'orthostatic-hypotension'). AdisBase search terms were 'Fluoxetine' or 'LY 110140' and ('stroke' or 'cardiovascular-disease' or 'cardiovascular-disorders' or 'cancer' or 'HIV' or 'acquired-immunodeficiency-syndrome' or 'diabetes-mellitus' or 'orthostatic-hypotension'. Searches were last updated 24 Oct 2000.
Selection: Studies in patients with depression and HIV/AIDS, diabetes mellitus, stroke or cancer who received fluoxetine. Inclusion of studies was based mainly on the methods section of the trials. When available, large, well controlled trials with appropriate statistical methodology were preferred. Relevant pharmacodynamic and pharmacokinetic data are also included.
Index terms: fluoxetine, comorbid physical illness, depression, pharmacodynamics, pharmacokinetics, therapeutic use.

Contents

Roxane Labs., Inc.
Exhibit 1013
Page 004

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

Summary

Abstract

Fluoxetine is a potent and selective inhibitor of neuronal serotonin (5-hydroxytryptamine) reuptake. Fluoxetine reduces food, energy and carbohydrate intake and increases resting energy expenditure, which may account for the moderate and transient bodyweight loss observed with its use. Glucose tolerance and/or hypoglycaemia in patients with type 2 diabetes mellitus improve with fluoxetine therapy.

The ability of fluoxetine to inhibit cytochrome P450 (CYP) isoenzymes (CYP2D6, CYP2C and CYP3A4), is potentially important for patients with physical illness who may be taking multiple concomitant medications.

Fluoxetine was more effective than placebo in 2 double-blind, randomised trials, and according to limited data appears to be equally effective compared with other SSRIs and tricyclic antidepressants (TCAs), in the treatment of depression in patients with HIV/AIDS. The efficacy of fluoxetine is also superior to that of placebo in the treatment of depression in patients with diabetes mellitus and stroke as shown in double-blind randomised trials, although its efficacy relative to that of nortriptyline in stroke is uncertain. Fluoxetine had similar efficacy to that of desipramine in patients with cancer, with improved Hamilton Depression Rating Scale and quality-of-life scores from baseline; however, the drug was not more effective than placebo in a double-blind randomised trial.

Medically healthy individuals tolerate fluoxetine well. Like other SSRIs, fluoxetine lacks the anticholinergic, cardiovascular, sedative and weight-increasing properties of TCAs, and is safer in overdose than TCAs and monoamine

© Adis International Limited. All rights reserved.

Roxane Labs., Inc.
Exhibit 1013
Page 005

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.