CENTER FOR DRUG EVALUATION AND RESEARCH

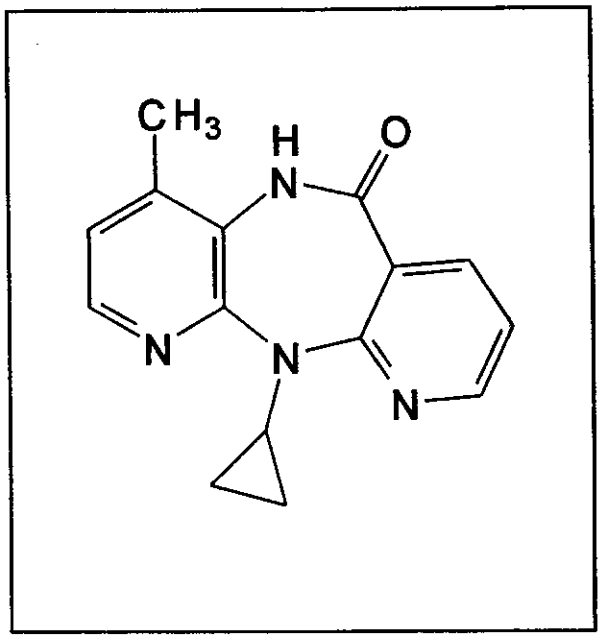
APPLICATION NUMBER:

20-636 /S-017
20-933 /S-007

PHARMACOLOGY REVIEW

PHARMACOLOGIST'S REVIEW

NDA: 20-636.SE7.017
Date Submitted: May 31, 2001
Date Assigned: June 5, 2001
Date Review Completed: July 23, 2001
DAVDP
HFD-530



SPONSOR: Boehringer Ingelheim
Pharmaceuticals, Inc.
900 Ridgebury Road
PO Box 368
Ridgefield, Connecticut 06877

INFORMATION TO SPONSOR: No

DRUG: VIRAMUNE®
USAN Names: Nevirapine
Code Name: BIRG 587 BS
Other Names: NVP, BIRG 587
Chemical Name (USAN): A: 6H-Dipyrido[3,2-b:2'3'-e][1,4]diazepin-6-one,11-cyclopropyl-5,11-dihydro-4-methyl B: 11-Cyclopropyl-5,11-dihydro-4-methyl-6H-dipyrido[3,2-b:2'3'-e][1,4]diazepin-6-one

CAS Registry:	129618-40-2
Molecular Formula:	$C_{15}H_{14}N_4O$
Molecular Weight:	266.31
Solubility:	0.1 mg/ml in water at 25°C
Melting Point:	247 - 249°C
Physical Description:	an off-white crystalline powder

INDICATION: Combination of Nevirapine with ddI and ZDV in previously treated HIV patients for whom current therapy is deemed inadequate.

RELATED NDAs/INDs: 36,026

ROUTE OF ADMINISTRATION: Oral

PROPOSED TREATMENT REGIMEN: 200 mg/day in combination with nucleoside analogs.

INTRODUCTION AND DRUG HISTORY:

Viramune® (nevirapine) is an approved drug that represents a class of non-nucleoside compounds that inhibits reverse

transcriptase (RT) activity of human immunodeficiency virus-type 1 (HIV-1). Nevirapine was chosen from a series of dipyridodiazepinone inhibitors of HIV-1 RT which were identified from a synthetic program of muscarinic receptor antagonists by random screening. Nevirapine does not inhibit human DNA polymerases α, ß, δ or γ to any great extent. Nevirapine is currently approved for use "in combination with nucleoside analogues for the treatment of HIV-1 infected adults who have experienced clinical and/or immunologic deterioration." Presently, the sponsor has submitted an application for full or "traditional" approval of Viramune® tablets.

TOXICOLOGY AND PHARMACOKINETICS:

There are no Pharm/tox issues associated with this compound. For details, please see original review of the NDA.

CONCLUSIONS:

No regulatory actions or communications regarding Pharm/Tox are required at this time.

Pritam S. Verma, Ph.D.
Reviewing Pharmacologist

Concurrences:
HFD-530/JFarrelly
HFD-530/PVerma

Disk
HFD-530/JFarrelly

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/s/

Pritam Verma
7/23/01 01:56:24 PM
PHARMACOLOGIST

James Farrelly
7/25/01 07:57:19 AM
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