

**CENTER FOR DRUG
EVALUATION AND
RESEARCH**

Approval Package for:

APPLICATION NUMBER:

81-051/S-003

Trade Name: Lortab Elixir

Generic Name: Hydrocodone Bitartrate and
Acetaminophen Elixir; 7.5mg/500mg per
15 mL

Sponsor: Mikart, Inc.

Approval Date: March 6, 1996

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

81-051/S-003

CONTENTS

Reviews / Information Included in this ANDA Review.

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Microbiology Review(s)	
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**CENTER FOR DRUG
EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

81-051/S-003

APPROVAL LETTER

ANDA 81-051/S-003

Mikart, Inc.
Attention: Cerie B. McDonald
1750 Chattahoochee Avenue, N.W.
Atlanta, Georgia 30318-2112

MAR 6 1996

Dear Madam:

This is in reference to your supplemental new drug application dated January 19, 1995, submitted pursuant to 21 CFR 314.70(c) (Special Supplement - Changes Being Effected) regarding your abbreviated new drug application for Lortab[®] Elixir (Hydrocodone Bitartrate and Acetaminophen Elixir) 7.5 mg/500 mg per 15 mL.

Reference is also made to your amendment dated July 24, 1995.

The supplemental application provides for carton labeling for the 30 mL sample bottle.

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

Jerry Phillips 3/6/96
Jerry Phillips

Acting Director

Division of Labeling and Program Support

Office of Generic Drugs

Center for Drug Evaluation and Research

cc: ANDA 81-051/S-003
Dup/Division File *John Muir 3/5/96*
HFD-613/AVezza/JGrace (no cc:)
HFD-600/RF *AVezza 2/26/96*
HFD-82
aev 2/26/96/ see x:\...ltrs&rev\81051S03.AP
Approval Letter - Single Supplement

**CENTER FOR DRUG
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APPLICATION NUMBER:

81-051/S-003

FINAL PRINTED LABELING

Mango 81-05 |

504



PHARMACIST: Dispense in a tight, light-resistant container with a child-resistant closure.

NDC 50474-909-28 1 Gallon (3785 mL)

USUAL DOSAGE: See package insert for complete dosage recommendations.

Store at controlled room temperature, 15°-30°C (59°-86°F).

Lortab® Elixir

MAR 6 1996

APPROVED

HYDROCODONE BITARTRATE AND ACETAMINOPHEN ELIXIR

2.5 mg/500 mg per 15 mL

Warning: May be habit forming.

Contains:	Per 5 mL	Per 15 mL
Hydrocodone*		
Bitartrate	2.5 mg	7.5 mg
*WARNING: May be habit forming.		
Acetaminophen	167 mg	500 mg
Alcohol	7%	7%



N 3 50474-909-28 7

Lot No.:
Exp. Date:

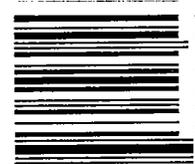
Manufactured for
Whitby Pharmaceuticals, Inc.
Richmond, VA 23220
by **Mikart, Inc.**
Atlanta, GA 30318

CAUTION: Federal law prohibits dispensing without prescription.

Rev. 11/94
Code 540A28
P/N 4G12025

Lot No.:
Exp. Date:

Contains:	Per 5 mL	Per 15 mL
Hydrocodone*		
Bitartrate	2.5 mg	7.5 mg
*WARNING: May be habit forming.		
Acetaminophen	167 mg	500 mg
Alcohol	7%	7%



N 3 50474-909-28 7

Manufactured for
Whitby Pharmaceuticals, Inc.
Richmond, VA 23220
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Atlanta, GA 30318

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Rev. 11/94
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Exp. Date:

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Hydrocodone*		
Bitartrate	2.5 mg	7.5 mg
*WARNING: May be habit forming.		
Acetaminophen	167 mg	500 mg
Alcohol	7%	7%



N 3 50474-909-28 7

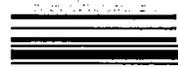
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Whitby Pharmaceuticals, Inc.
Richmond, VA 23220
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Atlanta, GA 30318

Contains:	Per 5 mL	Per 15 mL
Acetaminophen	167 mg	500 mg
Alcohol	7%	7%

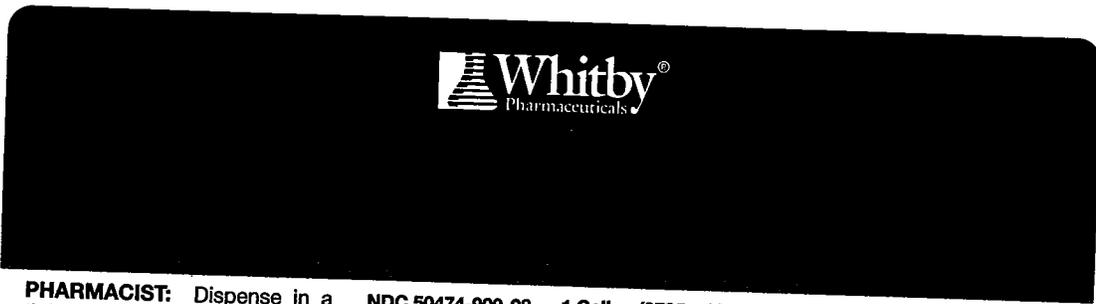


N 3 50474-909-28 7

CAUTION: Federal law prohibits dispensing without prescription.

Rev. 11/94
Code 540A28
P/N 4G12025

orig 81-051
504



PHARMACIST: Dispense in a tight, light-resistant container with a child-resistant closure.

NDC 50474-909-28 1 Gallon (3785 mL)

USUAL DOSAGE: See package insert for complete dosage recommendations.

Store at controlled room temperature, 15°-30°C (59°-86°F).

Lortab® Elixir

HYDROCODONE BITARTRATE AND ACETAMINOPHEN ELIXIR
2.5 mg/500 mg per 15 mL

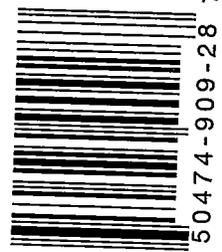
MAR 6 1996

APPROVED

Warning: May be habit forming.

Lot No.:
Exp. Date:

Contains:	Per 5 mL	Per 15 mL
Hydrocodone Bitartrate	2.5 mg	7.5 mg
Acetaminophen	167 mg	500 mg
Alcohol	7%	7%

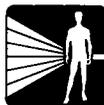
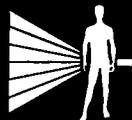


Manufactured for
Whitby Pharmaceuticals, Inc.
Richmond, VA 23220
by **Mikart, Inc.**
Atlanta, GA 30318

CAUTION: Federal law prohibits dispensing without prescription.

Rev. 11/94
Code 540A28
P/N 4G12025

LORTAB ELIXIR



LORTAB ELIXIR MAR 6 1996

HYDROCODONE* BITARTRATE AND ACETAMINOPHEN ELIXIR
7.5 mg/500 mg per 15 mL, *Warning: May be habit forming

Usual Dosage: See enclosed package insert for complete dosage recommendations.

Store at controlled room temperature
15°-30°C (59°-86°F).

Contains six 1 fl oz bottles.

Physician sample—not to be sold.

Package not child-resistant.

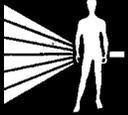
APPROVED

Lot:

Exp:



Manufactured for Whitby Pharmaceuticals, Inc.,
Richmond, VA 23220, by Mikart, Inc., Atlanta, GA 30318
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Printed in USA. P/N 4R12025 Rev. 12/94



LORTAB ELIXIR

LORTAB ELIXIR

HYDROCODONE* BITARTRATE AND ACETAMINOPHEN ELIXIR
7.5 mg/300 mg per 15 mL

*Warning: May be habit forming

Six 15 mL bottles

Caution: Federal law prohibits dispensing without prescription.
This is a Schedule II controlled substance.

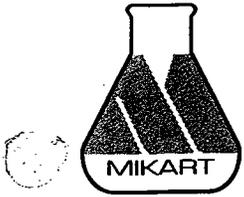


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RESEARCH**

APPLICATION NUMBER:

81-051/S-003

CORRESPONDENCE



MIKART, INC.
PHARMACEUTICAL MANUFACTURERS

orig

*Approved letter
Wagner 2/26/96*

July 24, 1995

Mr. Douglas L. Sporn, Acting Director
Office of Generic Drugs
Document Control Room
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II (MPN II)
Room 150
7500 Standish Place
Rockville, MD 20855-2773

SLOW 3AL
NDA SUPPL AMENDMENT

Re: ANDA 81-051 (S-003) Lortab Elixir (Hydrocodone Bitartrate
and Acetaminophen Elixir 7.5 mg/500 mg per 15 mL)
Amendment to a Supplemental Application
SPECIAL SUPPLEMENT: CHANGES BEING EFFECTED

Dear Mr. Sporn:

Mikart has received your letter dated June 8, 1995 regarding the
above supplemental application. Enclosed please find twelve
copies of final printed tray labeling. This tray will be intro-
duced July 10, 1995.

Sincerely,

Cerie B. McDonald
Executive Vice-President

CBM/sw

Enc.

RECEIVED

JUL 27 1995

GENERIC DRUGS

Handwritten signature and date: 9/28/95