



TRANSMITTED BY FACSIMILE

Anthony J. Corrado
Program Director
Drug Regulatory Affairs
Roche Laboratories, Inc.
340 Kingsland Street
Nutley, New Jersey 07110-1199

Re: NDA # 20-697
Tasmar (tolcapone) Tablets
MACMIS # 10175

Dear Mr. Corrado:

This letter notifies Roche Laboratories, Inc. (Roche) of violative promotional materials for Tasmar (tolcapone) Tablets. These materials are in violation of the Federal Food, Drug, and Cosmetic Act and applicable regulations because they contain misleading claims and lack risk information. The violative materials include physician starter packs, bottle holders and packers (ID #s 26106877-1197, 25708261-0897, 25910458-1197, and 25708282-0697).

Specifically, the Division of Drug Marketing, Advertising, and Communications (DDMAC) objects to the following:

Misleading Claims

“Introducing...”

Tasmar was launched in April 1998. This “introducing” claim is misleading because Tasmar is not a new drug and its introduction period is over.

“The first and only COMT inhibitor”

“Completely new kind...”

Since, a new COMT inhibitor was approved in October 1999, Tasmar has not been the only COMT inhibitor. Thus, it is misleading to refer to Tasmar as “the first and only...” Similarly, Tasmar is not a “completely new kind of treatment for Parkinson’s Disease.”

Lack of Fair Balance

The cited Tasmar promotional materials have insufficient risk information to balance the claims about the drug. Tasmar is a second line drug for Parkinson's Disease, and has a boxed warning about the risk of fatal, acute fulminant liver failure and the need for patient monitoring. This important risk information is not presented in the materials. In addition, the statement "as with all drugs, side effects may occur with Tasmar" is not adequate as fair balance and minimizes the risks associated with Tasmar.

Failure to File

Our records indicate that these promotional materials have not been submitted to DDMAC on FORM FDA 2253 as stipulated in 21 CFR §314.81(b)(3)(i) that states that the sponsor shall submit all labeling and advertising at the time of initial dissemination.

Requested Actions

To address these objections, DDMAC requests that Roche:

1. Immediately discontinue the use of these starter kit and sample materials, as well as any other promotional material and practices with the same or similar messages.
2. Respond to this letter by August 16, 2001. Your response should include a statement of your intent to comply with the above, a list of all promotional materials with the same or similar issues, and your methods for discontinuing these promotional materials.
3. Review all disseminated promotional material and submit outstanding materials to DDMAC on Form FDA 2253, as required.

If you have any questions or comments, please contact Dr. Lisa Stockbridge by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-42, rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds you that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID # 10175 in addition to the NDA number.

Sincerely,

{See appended electronic signature page}

Lisa L. Stockbridge, Ph.D.
Regulatory Reviewer
Division of Drug Marketing,
Advertising and Communications

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Lisa Stockbridge
8/2/01 04:28:55 PM

Label - 100mg Tablets, 90's

NDC 0004-5920-01



TASMAR[®]
(tolcapone)

100 mg

R only.

90 Tablets



Each tablet contains 100 mg tolcapone.
USUAL DOSAGE: For dosage recommendations and
other important prescribing information,
read accompanying insert.
ROCHE LABORATORIES INC.
Nutley, New Jersey 07110



0004-5920-01

Dispense in light containers
as defined in USP/NF.
STORE AT CONTROLLED ROOM TEMPERATURE
20° TO 25°C (68° TO 77°F) [see USP].

LOT EXP.

28133459-0698

Label - 100mg Tablets, 15's

NDC 0004-5920-38



TASMAR[®]
(tolcapone)

100 mg

Physician's Supply -
NOT FOR SALE

CAUTION: Federal law prohibits
dispensing without prescription.

15 Tablets



Each tablet contains 100 mg tolcapone.
USUAL DOSAGE: See package insert.

ROCHE LABORATORIES INC.
Nutley, New Jersey 07110



0004-5920-38

STORE AT CONTROLLED ROOM TEMPERATURE
20° TO 25°C (68° TO 77°F) [see USP].

LOT

EXP.

25810023-1197

Bottle Holder - 100mg Tablets, 15's
(continued on next page)

NDC 0004-5920-38

INTRODUCING



THE FIRST
COMT INHIBITOR

TASMAR[®]
tolcapone 100mg
tablets

Please see the reverse side for
additional information.

Each tablet contains 100 mg tolcapone.

Usual Dosage: For dosage recommendations
and other important prescribing information, read
accompanying insert.

STORE AT CONTROLLED ROOM TEMPERATURE
20° TO 25°C (68° TO 77°F) [see USP].

Caution: Federal law prohibits
dispensing without prescription.



25105877



INTRODUCING

TASMAR[®]
tolcapone

100 mg

Physician's Starter Pack
NOT FOR SALE

15 TABLETS

Bottle Holder – 100mg Tablets, 15's
(continued from previous page)

TASMAR[®] (tolcapone) is the first and only COMT inhibitor, a completely new kind of treatment for Parkinson's disease.

As with all drugs, side effects may occur with TASMAR. In some cases, a reduction in carbidopa/levodopa (eg, Sinemet[®] or Sinemet[®] CR)^{*} may be needed.

If you experience any change in your condition or have questions about your condition or treatment, contact your doctor.

Your physician has been provided with TASMAR complete product information.

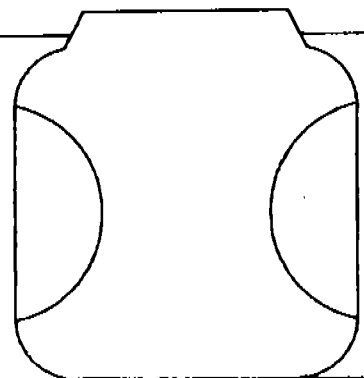
* Sinemet and Sinemet CR are registered trademarks of DuPont Pharma.

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26106877-1197



Pharmaceuticals

Roche Laboratories Inc.
340 Kingsland Street
Nutley, New Jersey 07110-1198



Packer - 100mg Tablets, 15's
(continued on next page)



INTRODUCING
THE FIRST COMT INHIBITOR

Roche Pharmaceuticals
340 Kingsland Street
Nutley, New Jersey 07110-1188

25708281-0287

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Please see accompanying complete product information.

NAME _____
TELEPHONE _____

For additional TASMAR® (tolcapone) starter packs, please contact
your Roche representative.

INTRODUCING
THE FIRST COMT INHIBITOR



TASMAR[®]
TOLCAPONE 100 mg

INTRODUCING

The first COMT
inhibitor

Packer - 100mg Tablets, 15's
(continued from previous page)

THE FIRST COMT INHIBITOR

INTRODUCING
THE FIRST COMT INHIBITOR

Label - 200mg Tablets, 90's

NDC 0004-5921-01



TASMAR[®]
(tolcapone)

200 mg

R_x only.

90 Tablets



Each tablet contains 200 mg tolcapone.
USUAL DOSAGE: For dosage recommendations and
other important prescribing information,
read accompanying insert.
ROCHE LABORATORIES INC.
Nutley, New Jersey 07110



0004-5921-01

Dispense in light containers
as defined in USP&NF.
STORE AT CONTROLLED ROOM TEMPERATURE
20° to 25°C (68° to 77°F) [see USP].

27420598-0898

LOT

EXP.

Label - 200mg Tablets, 15's

NDC 0004-5921-38



TASMAR[®]
(tolcapone)

200 mg Physician's Supply -
NOT FOR SALE

CAUTION: Federal law prohibits
dispensing without prescription.

15 Tablets



Each tablet contains 200 mg tolcapone.
USUAL DOSAGE: See package insert.
ROCHE LABORATORIES INC.
Nutley, New Jersey 07110



0004-5921-38

STORE AT CONTROLLED ROOM TEMPERATURE
20° TO 25°C (68° TO 77°F) [see USP].

LOT EXP.

25633763-1197

Bottle Holder – 200mg Tablets, 15's
(continued on next page)

NDC 0004-5921-39

INTRODUCING

THE FIRST
COMT INHIBITOR
TASMAR[®]
tolcapone 200^{mg}
tablets

Please see the reverse side for
additional information.

Each tablet contains 200 mg tolcapone.

Usual Dosage: For dosage recommendations
and other important prescribing information, read
accompanying insert.

STORE AT CONTROLLED ROOM TEMPERATURE
20° TO 25°C (68° TO 77°F) [see USP].

Caution: Federal law prohibits
dispensing without prescription.



INTRODUCING

TASMAR[®]
tolcapone 200 mg

200 mg

Physician's Starter Pack
NOT FOR SALE

15 TABLETS

Bottle Holder – 200mg Tablets, 15's
(continued from previous page)

TASMAR[®] (tolcapone)
first and only COMT inhibitor,
a completely new kind
of treatment for
Parkinson's disease.

As with all drugs, side effects may occur with TASMAR. In some cases, a reduction in carbidopa/levodopa (eg. Sinemet[®] or Sinemet[®] CR)* may be needed.

If you experience any change in your condition or have questions about your condition or treatment, contact your doctor.

Your physician has been provided with TASMAR complete product information.

* Sinemet and Sinemet CR are registered trademarks of DuPont Pharma.

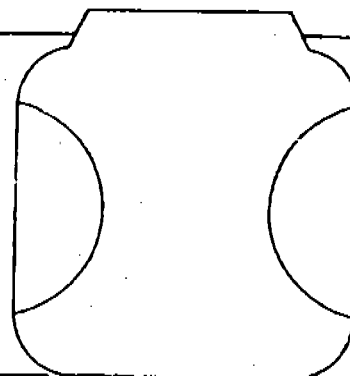
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25910458-1197

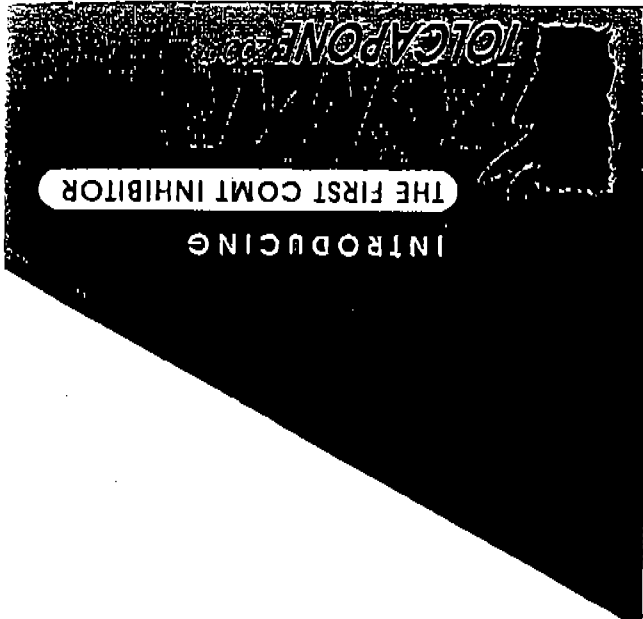


Pharmaceuticals

Roche Laboratories Inc.
340 Kingsland Street
Nutley, New Jersey 07110-1109



Packer - 200mg Tablets, 15's
(continued on next page)



Roche Laboratories Inc.
240 Kingland Blvd
Nutley, New Jersey 07110-1780



2570282-0007

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Please see accompanying complete product information.

For additional TASMAR® (tolcapone) starter packs, please contact
your Roche representative:
NAME _____
TELEPHONE _____

INTRODUCING
THE FIRST **COMT** INHIBITOR



TASMAR
TOLCAPONE 200 mg

INTRODUCING
The first **COMT**
inhibitor

Packer - 200mg Tablets, 15's
(continued from previous page)

THE FIRST COMT INHIBITOR

TOLCAPONE[®]

INTRODUCING

THE FIRST COMT INHIBITOR

TASMAR[®]
TOLCAPONE 200mg