

**CENTER FOR DRUG
EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

65-156

CSO LABELING REVIEW(S)

**REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH**

ANDA Number: **65-156**

Date of Submission: **February 10, 2003**

Applicant's Name: **Ranbaxy Laboratories Limited**

Established Name: **Minocycline Hydrochloride Tablets USP, 50 mg, 75 mg and 100 mg**

Labeling Deficiencies:

1. GENERAL COMMENTS

- a. Revise the storage temperature recommendation throughout your labels and labeling as follows:

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

- b. Please note that when Minocin® Tablets were marketed only the 100 mg strength tablets were scored. Delete the score from the 50 mg and 75 mg tablets.

2. CONTAINER 6s and 500s

- a. See GENERAL COMMENTS (1) (a) above.

- b. "Dispense in a tight, light-resistant container as defined in the USP." [add "the"]

- c. We note that a portion of the storage temperature recommendation as seen on the 6 tablet container size for the 100 mg tablet strength appears in bold print. Please be consistent throughout the labels and labeling when indicating the storage temperature recommendation.

- d. We note that the DOSAGE AND ADMINISTRATION section does not support a treatment which consists of a total of 6 tablets of any of the three strengths. Is your container size of 6s intended to be used as samples?

3. INSERT

a. DESCRIPTION

First line - "... hydrochloride, a semisynthetic derivative of tetracycline, is 4, ..."

b. CLINICAL PHARMACOLOGY

Microbiology, first paragraph, third line - "... have a similar antimicrobial spectrum of ..."

c. INDICATIONS AND USAGE

- i. First listing

- A). "rickettsiae" [not in italic print]
- B). "Nongonococcal urethritis, endocervical, or rectal infections in adults caused by *Ureaplasma urealyticum* or *Chlamydia trachomatis*."
- ii. Statement beginning "Uncomplicated urethritis in men ..."
- A). Delete " _____"
- B). Relocate this statement to appear before "Infections in women caused by ..."
- iii. "Syphilis caused by *Treponema pallidum* subspecies *pallidum*."
- iv. "Yaws caused by *Treponema pallidum* subspecies *pertenue*."
- v. Paragraph beginning "Oral minocycline is indicated in ...", second sentence - "carriers" [plural]
- d. WARNINGS
 - i. First paragraph
 - A). First sentence - Delete _____
 - B). Second sentence - "PREGNANCY, OR" [add comma]
 - ii. Third paragraph, second sentence - "... in the fibula ..." [add "the"]
 - iii. Penultimate paragraph, last sentence - "... reported rarely with ..."
 - iv. Last paragraph, first sentence - "lightheadedness" [delete _____]
- e. PRECAUTIONS
 - i. General - Delete the third paragraph [_____]
 - ii. Information For Patients
 - A). First paragraph, last sentence - "... reported rarely with ..."
 - B). Last paragraph - "Concurrent use of tetracyclines with oral contraceptives may render oral contraceptives less ..."
 - iii. Laboratory Tests - revise this subsection as seen below:

In long-term therapy, periodic laboratory evaluation of organ systems, including hematopoietic, renal, and hepatic, should be performed.

All patients with gonorrhoea should have a serologic test for syphilis at the time of diagnosis. Patients treated with minocycline should have a follow-up serologic test for syphilis after 3 months.
 - iv. Drug Interactions
 - A). Third paragraph - "... of oral tetracyclines is ..."

- B). Delete the last paragraph - _____
- v. Pregnancy - Delete the first two paragraphs _____
- vi. Pediatric Use - Delete "i _____ [Leave "(See WARNINGS)"]
- vii. Geriatric Use
 - A). Upper case "U" in the title.
 - B). First sentence - "... of oral minocycline ..."

f. ADVERSE REACTIONS

- i. Delete " _____
- ii. Gastrointestinal
 - A). First line - Delete ' _____
 - B). Second line - Delete " _____
 - C). Third line - "... in the anogenital region, and increases in liver enzymes have been reported. Rarely, hepatitis and liver failure have been reported. These reactions have been caused by both the oral and parenteral administration of tetracyclines. Rare instances of esophagitis and ..."
- iii. Delete ' _____
- iv. Delete " _____
- v. Skin
 - A). Delete " _____
 - B). Paragraph beginning "Maculopapular ..."
 - 1). Second sentence - "...been reported but is uncommon."
 - 2). Third sentence - "... have been rarely reported."
 - 3). Fifth sentence - "... and, rarely, Stevens-Johnson ..."
- vi. Delete " _____
- vii. Renal toxicity
 - A). Delete " _____
 - B). "... (see WARNINGS.). Acute renal failure has been rarely reported and, in most cases, has been reversible."
- viii. Delete " _____

- ix. Hypersensitivity reactions
 - A). Second line - Delete ' _____
 - B). Third line - "... erythematous, and rarely, pulmonary ..."
 - C). Last sentence - "A lupus-like syndrome and serum sickness-like reactions also have been reported."
- x. Blood
 - A). Delete " _____
 - B). "Hemolytic" [upper case "H"]
 - C). Delete ' _____
- xi. Central nervous system - Delete the first sentence.
- xii. Other
 - A). First paragraph, last sentence - "Very rare cases of abnormal ..."
 - B). Interchange the positioning of the second and third paragraphs.
 - C). "Tinnitus and decreased hearing have been rarely reported ..."
 - D). "Tooth discoloration in pediatric patients ... and also, rarely, in adults ..."
- xiii. Delete the rest of the ADVERSE REACTIONS section [_____

g. OVERDOSAGE

- i. Delete the first two paragraphs.
- ii. "... measures. Minocycline is not removed in significant quantities by hemo dialysis or peritoneal dialysis.

h. DOSAGE AND ADMINISTRATION

- i. Second paragraph - "... tablets should be taken at least one hour before meals or 2 hours after meals . (see **CLINICAL PHARMACOLOGY**).
- ii. Delete the third paragraph [_____
- iii. For Pediatric Patients Above 8 Years of Age - "Usual pediatric dose: 4 mg/kg initially followed by 2 mg/kg every 12 hours."
- iv. Adults
 - A). Third paragraph, first sentence - "... of minocycline hydrochloride should be ..."
 - B). *Mycobacterium marinum* infections: - "... has been used ..."

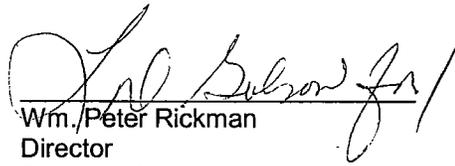
- C). "Uncomplicated urethral, endocervical, or rectal infection in adults caused by ..."
- v. Last sentence of section - "... the total dosage should be decreased by either reducing the recommended individual doses and/or by extending the time intervals between doses."
- i. HOW SUPPLIED
See GENERAL COMMENTS above.
- j. ANIMAL PHARMACOLOGY AND TOXICOLOGY
First and fifth lines - "Minocycline hydrochloride has been ..."

Please revise your container labels and insert labeling, as instructed above, and submit 12 copies of each in final print.

Prior to approval, it may be necessary to revise your labeling subsequent to approved changes for the reference listed drug. In order to keep ANDA labeling current, we suggest that you subscribe to the daily or weekly updates of new documents posted on the CDER web site at the following address -

<http://www.fda.gov/cder/cdernew/listserv.html>

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.


Wm. Peter Rickman
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

BASIS OF APPROVAL:

APPROVAL SUMMARY (List the package size, strength(s), and date of submission for approval):

Do you have 12 Final Printed Labels and Labeling? Yes No If no, list why:

Container Labels: 6s and 500s

Professional Package Insert Labeling:

Revisions needed post-approval:

BASIS OF APPROVAL:

Was this approval based upon a petition? No

What is the RLD on the 356(h) form: Minocin Pellet-Filled Capsules

NDA Number: 50-649

NDA Drug Name: Minocin (minocycline hydrochloride) Capsules

NDA Firm: Lederle Pharmaceutical Division

Date of Approval of NDA Insert and supplement #: 5/31/02 (S-011)

Has this been verified by the MIS system for the NDA? Yes

Was this approval based upon an OGD labeling guidance? No

Basis of Approval for the Container Labels: side-by-sides

Other Comments

REVIEW OF PROFESSIONAL LABELING CHECK LIST

Established Name	Yes	No	N.A
Different name than on acceptance to file letter?		X	
Is this product a USP item? If so, USP supplement in which verification was assured. USP 25	X		
Is this name different than that used in the Orange Book?		X	
If not USP, has the product name been proposed in the PF?			X
Error Prevention Analysis			
Has the firm proposed a proprietary name? NO.		X	
Packaging			
Is this a new packaging configuration, never been approved by an ANDA or NDA? If yes, describe in FTR.	X		
Is this package size mismatched with the recommended dosage? If yes, the Poison Prevention Act may require a CRC.	X		
Does the package proposed have any safety and/or regulatory concerns?		X	
Conflict between the DOSAGE AND ADMINISTRATION and INDICATIONS sections and the packaging configuration?	X		
Is the strength and/or concentration of the product unsupported by the insert labeling?		X	
Is the color of the container (i.e. the color of the cap of a mydriatic ophthalmic) or cap incorrect?			X
Individual cartons required? Issues for FTR: Innovator individually cartoned? Light sensitive product which might require cartoning? Must the package insert accompany the product?		X	
Are there any other safety concerns?		X	
Labeling			
Is the name of the drug unclear in print or lacking in prominence? (Name should be the most prominent information on the label).		X	
Has applicant failed to clearly differentiate multiple product strengths?		X	
Is the corporate logo larger than 1/3 container label? (No regulation - see ASHP guidelines)		X	
Does RLD make special differentiation for this label? (i.e., Pediatric strength vs Adult; Oral Solution vs Concentrate, Warning Statements that might be in red for the NDA)		X	
Is the Manufactured by/Distributor statement incorrect or falsely inconsistent between labels and labeling? Is "Jointly Manufactured by..." statement needed?		X	
Failure to describe solid oral dosage form identifying markings in HOW SUPPLIED?		X	
Has the firm failed to adequately support compatibility or stability claims which appear in the insert labeling? Note: Chemist should confirm the data has been adequately supported.		X	
Scoring: Describe scoring configuration of RLD and applicant (page #) in the FTR			
Is the scoring configuration different than the RLD?		X	
Has the firm failed to describe the scoring in the HOW SUPPLIED section?		X	

Inactive Ingredients: (FTR: List page # in application where inactives are listed)			
Does the product contain alcohol? If so, has the accuracy of the statement been confirmed?		X	
Do any of the inactives differ in concentration for this route of administration?		X	
Any adverse effects anticipated from inactives (i.e., benzyl alcohol in neonates)?		X	
Is there a discrepancy in inactives between DESCRIPTION and the composition statement?		X	
Has the term "other ingredients" been used to protect a trade secret? If so, is claim supported?		X	
Failure to list the coloring agents if the composition statement lists e.g., Opacode, Opaspray?		X	
USP Issues: (FTR: List USP/NDA/ANDA dispensing/storage recommendations)			
Do container recommendations fail to meet or exceed USP/NDA recommendations? If so, are the recommendations supported and is the difference acceptable?		X	
Because of proposed packaging configuration or for any other reason, does this applicant meet fail to meet all of the unprotected conditions of use of referenced by the RLD?		X	
Does USP have labeling recommendations? If any, does ANDA meet them?		X	
Is the product light sensitive? If so, is NDA and/or ANDA in a light resistant container?	X?	X?	
Failure of DESCRIPTION to meet USP Description and Solubility information? If so, USP information should be used. However, only include solvents appearing in innovator labeling.		X	
Bioequivalence Issues: (Compare bioequivalency values: insert to study. List Cmax, Tmax, T 1/2 and date study acceptable)			
Insert labeling references a food effect or a no-effect? If so, was a food study done?	X		
Has CLINICAL PHARMACOLOGY been modified? If so, briefly detail where/why.		X	
Patent/Exclusivity Issues?: FTR: Check the Orange Book edition or cumulative supplement for verification of the latest Patent or Exclusivity. List expiration date for all patents, exclusivities, etc. or if none, please state.			

FOR THE RECORD:

- Review based on the labeling of Minocin Pellet-Filled Capsules, revised ; approved 5-31-02 (S-011). We have labeling for S-011 which has "strike-outs" and "double underlining" for relevant text -- this insert does not match the insert sent to us by AntilInfectives. Confirmation "over the phone" from Judit Milstein, the PM for this drug product, was obtained that we are to use the labeling which has the statement "FDA Final Revised Labeling Document Dated 19 Aug 1998" lined out at the top. Dr J. Council has e-mailed J. Milstein so that a "hard copy" may be placed in the file record for this drug product.

2. Patent/ Exclusivities
Patent Data – 50649

No	Expiration	Use Code	Use	File
None				

Exclusivity Data - 50649

Code/sup	Expiration	Use Code	Description	Labeling Impact
None			There is no unexpired exclusivity for this product	

- Storage Conditions:
 NDA - Store at controlled room temperature 20° - 25°C (68° - 77°F). Protect from light, moisture and excessive heat.
 ANDA - Store at controlled room temperature 20° - 25°C (68° - 77°F). Protect from light, moisture and excessive heat. **I have asked the firm to revise to "Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]"**.
 USP -

- Dispensing Recommendations:
 NDA - Dispense in a tight, light-resistant container as defined in the USP.
 ANDA - Dispense in a tight, light-resistant container as defined in USP.
 USP - Preserve in tight, light-resistant containers.

5. Scoring:
NDA - 50 mg [unscored] -- 100 mg [scored] - **Tablets discontinued not for safety or efficacy.**
ANDA - 50 mg, 75 mg, 100 mg [scored] but firm has been asked to delete the scoring from the 50 mg and 75 mg tablets and they have committed to do so.
6. The 75 mg tablet was acceptable thru a suitability petition.
7. Product Line:
The innovator markets their product (capsules) in bottles of 50s [100 mg] and bottles of 100s [50 mg]. The applicant proposes to market their product in bottles of 6s and 500s for all three strengths. All the containers are made of HDPE and they all have CRC caps [pp 2627-2628 -- Vol B 1.3 -- Section XIII].
8. The tablet debossings have been accurately described in the HOW SUPPLIED section as required by 21 CFR 206,et al. (Imprinting of Solid Oral Dosage Form Products for Human Use; Final Rule, effective 9/13/95) except that the 50 mg and 75 mg tablet descriptions say they have a bisect. The firm has committed to revise this. **See FOR THE RECORD # 5 above.**
9. Inactive Ingredients:
The listing of inactive ingredients in the DESCRIPTION section of the package insert appears to be consistent with the listing of inactive ingredients found in the statement of components and composition appearing on p 2068 -- Vol B 1.2 -- Section VII.
10. OHM Laboratories Inc. is the manufacturer [p 2190 -- Vol B 1.2 -- Section IX].
11. With respect to the maximum recommended dose of 300 mg/day of drug product, the maximum amount of iron oxide yellow per day per the D & A section of the insert is _____ [see p 2071 Vol B 1.2] which is less than the permitted limit of 5 mg of iron per day as cited in 21 CFR 73.1200 (c). **Please note that the calculated amount of _____ is of "iron oxide yellow" -- there is less than this amount of "iron" that would be taken at the maximum dose per day.**

Date of Review: 9-18-03

Date of Submission: 2-10-03

Primary Reviewer: Adolph Vezza

Date:

Team Leader: Lillie Golson

Date:

cc: ANDA: 65-156
DUP/DIVISION FILE
HFD-613/AVezza/LGolson (no cc)
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Review

**APPEARS THIS WAY
ON ORIGINAL**

**APPROVAL SUMMARY
 REVIEW OF PROFESSIONAL LABELING
 DIVISION OF LABELING AND PROGRAM SUPPORT
 LABELING REVIEW BRANCH**

ANDA Number: **65-156**

Date of Submission: **October 10, 2003**

Applicant's Name: **Ranbaxy Laboratories Limited**

Established Name: **Minocycline Hydrochloride Tablets USP, 50 mg, 75 mg and 100 mg**

BASIS OF APPROVAL:

APPROVAL SUMMARY (List the package size, strength(s), and date of submission for approval):

Do you have 12 Final Printed Labels and Labeling? **Yes**

Container Labels: **500s**

Satisfactory in FPL as of October 10, 2003 submission [vol 2.1].

Professional Package Insert Labeling:

Satisfactory in FPL as of October 10, 2003 submission [vol 2.1 - rev 10-03 - FDA-02].

Revisions needed post-approval: **None**

BASIS OF APPROVAL:

Was this approval based upon a petition? **Yes (see FTR)**

What is the RLD on the 356(h) form: **Minocin Pellet-Filled Capsules**

NDA Number: **50-649**

NDA Drug Name: **Minocin (minocycline hydrochloride) Capsules**

NDA Firm: **Lederle Pharmaceutical Division**

Date of Approval of NDA Insert and supplement #: **5/31/02 (S-011)**

Has this been verified by the MIS system for the NDA? **Yes**

Was this approval based upon an OGD labeling guidance? **No**

Basis of Approval for the Container Labels: **side-by-sides**

Other Comments

REVIEW OF PROFESSIONAL LABELING CHECK LIST

Established Name	Yes	No	N.A
Different name than on acceptance to file letter?		X	
Is this product a USP item? If so, USP supplement in which verification was assured. USP 25	X		
Is this name different than that used in the Orange Book?		X	
Error Prevention Analysis			
Has the firm proposed a proprietary name? NO.		X	
Packaging			
Is this a new packaging configuration, never been approved by an ANDA or NDA? If yes, describe in FTR.	X		
Is this package size mismatched with the recommended dosage? If yes, the Poison Prevention Act may require a CRC.	X		
Does the package proposed have any safety and/or regulatory concerns?		X	
Conflict between the DOSAGE AND ADMINISTRATION and INDICATIONS sections and the packaging configuration?	X		
Is the strength and/or concentration of the product unsupported by the insert labeling?		X	
Is the color of the container (i.e. the color of the cap of a mydriatic ophthalmic) or cap incorrect?			X
Individual cartons required? Issues for FTR: Innovator individually cartoned? Light sensitive product which might require cartoning? Must the package insert accompany the product?		X	

Are there any other safety concerns?		X	
Labeling			
Is the name of the drug unclear in print or lacking in prominence? (Name should be the most prominent information on the label).		X	
Has applicant failed to clearly differentiate multiple product strengths?		X	
Is the corporate logo larger than 1/3 container label? (No regulation - see ASHP guidelines)		X	
Does RLD make special differentiation for this label? (i.e., Pediatric strength vs Adult; Oral Solution vs Concentrate, Warning Statements that might be in red for the NDA)		X	
Is the Manufactured by/Distributor statement incorrect or falsely inconsistent between labels and labeling? Is "Jointly Manufactured by...", statement needed?		X	
Failure to describe solid oral dosage form identifying markings in HOW SUPPLIED?		X	
Has the firm failed to adequately support compatibility or stability claims which appear in the insert labeling? Note: Chemist should confirm the data has been adequately supported.		X	
Scoring: Describe scoring configuration of RLD and applicant (page #) in the FTR			
Is the scoring configuration different than the RLD?		X	
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Inactive Ingredients: (FTR: List page # in application where inactives are listed)			
Does the product contain alcohol? If so, has the accuracy of the statement been confirmed?		X	
Do any of the inactives differ in concentration for this route of administration?		X	
Any adverse effects anticipated from inactives (i.e., benzyl alcohol in neonates)?		X	
Is there a discrepancy in inactives between DESCRIPTION and the composition statement?		X	
Has the term "other ingredients" been used to protect a trade secret? If so, is claim supported?		X	
Failure to list the coloring agents if the composition statement lists e.g., Opacode, Opaspray?		X	
USP Issues: (FTR: List USP/NDA/ANDA dispensing/storage recommendations)			
Do container recommendations fail to meet or exceed USP/NDA recommendations? If so, are the recommendations supported and is the difference acceptable?		X	
Because of proposed packaging configuration or for any other reason, does this applicant meet fail to meet all of the unprotected conditions of use of referenced by the RLD?		X	
Does USP have labeling recommendations? If any, does ANDA meet them?		X	
Is the product light sensitive? If so, is NDA and/or ANDA in a light resistant container?	X?	X?	
Failure of DESCRIPTION to meet USP Description and Solubility information? If so, USP information should be used. However, only include solvents appearing in innovator labeling.		X	
Bioequivalence Issues: (Compare bioequivalency values: insert to study. List Cmax, Tmax, T 1/2 and date study acceptable)			
Insert labeling references a food effect or a no-effect? If so, was a food study done?	X		
Has CLINICAL PHARMACOLOGY been modified? If so, briefly detail where/why.		X	
Patent/Exclusivity Issues?: FTR: Check the Orange Book edition or cumulative supplement for verification of the latest Patent or Exclusivity. List expiration date for all patents, exclusivities, etc. or if none, please state.			

FOR THE RECORD: (portions taken from previous review)

- Review based on the labeling of Minocin Pellet-Filled Capsules, revised ; approved 5-31-02 (S-011). We have labeling for S-011 which has "strike-outs" and "double underlining" for relevant text -- this insert does not match the insert sent to us by Antinfectives. Confirmation "over the phone" from Judit Milstein, the PM for this drug product, was obtained that we are to use the labeling which has the statement "FDA Final Revised Labeling Document Dated 19 Aug 1998" lined out at the top. Dr J. Council has e-mailed J. Milstein so that a "hard copy" may be placed in the file record for this drug product.
- Patent/ Exclusivities
Patent Data – 50649

No	Expiration	Use Code	Use	File
None				

Exclusivity Data - 50649

Code/sup	Expiration	Use Code	Description	Labeling Impact
None			There is no unexpired exclusivity for this product	

3. Storage Conditions:
 NDA - Store at controlled room temperature 20° - 25°C (68° - 77°F). Protect from light, moisture and excessive heat.
 ANDA - Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].. Protect from light, moisture and excessive heat.
 USP -
4. Dispensing Recommendations:
 NDA - Dispense in a tight, light-resistant container as defined in the USP.
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 ANDA - 50 mg, 75 mg, 100 mg [scored] but firm has been asked to delete the scoring from the 50 mg and 75 mg tablets and they have done so.
6. The 75 mg tablet was acceptable thru a suitability petition. Per the Federal Register Notice dated January 27, 1998 (Volume 63, Number 17) minocycline hydrochloride tablets were not discontinued due to safety or effectiveness. Last sentence of notice states "ANDA's that refer to minocycline hydrochloride tablets may be approved by the agency." [pp 11-12 - vol 1.1 - sec II]
7. Product Line:
 The innovator markets their product (capsules) in bottles of 50s [100 mg] and bottles of 100s [50 mg]. The applicant proposes to market their product in bottles of 500s for all three strengths. The firm originally submitted container labels of 6s but withdrew these - they were planning to distribute them as samples. All the containers are made of HDPE and they all have CRC caps [pp 2627-2628 -- Vol B 1.3 -- Section XIII].
8. The tablet debossings have been accurately described in the HOW SUPPLIED section as required by 21 CFR 206,et al. (Imprinting of Solid Oral Dosage Form Products for Human Use; Final Rule, effective 9/13/95).
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11. With respect to the maximum recommended dose of 300 mg/day of drug product, the maximum amount of iron oxide yellow per day per the D & A section of the insert is ~~5 mg~~ [see p 2071 Vol B 1.2] which is less than the permitted limit of 5 mg of iron per day as cited in 21 CFR 73.1200 (c). **Please note that the calculated amount of ~~5 mg~~ is of "iron oxide yellow" -- there is less than this amount of "iron" that would be taken at the maximum dose per day.**

Date of Review: 11-3-03

Date of Submission: 10-10-03

Primary Reviewer: Adolph Vezza

Date:

A. Vezza

11/6/03

Team Leader: Lillie Golson

Date:

Lillie Golson

11/6/03