



NDA 18-891/S-022

Boehringer Ingelheim Pharmaceuticals, Inc.  
Attention: Kelly Billingham  
900 Ridgebury Rd.  
P.O. Box 368  
Ridgefield, CT 06877

Dear Ms. Billingham:

Please refer to your electronic supplemental new drug application dated February 27, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Catapres-TTS (clonidine) 0.1, 0.2 and 0.3 mg Transdermal Patch.

This supplemental new drug application provides for electronic final printed labeling (FPL) revised, as requested in our information request letters dated March 19, 2002 and June 24, 2003, as follows:

Package Insert

1. The brand name "Catapres-TTS" was replaced with "CATAPRES-TTS" throughout the labeling.
2. Under the **DESCRIPTION** section, the brand name "CATAPRES" was added in front of the structural formula.
3. The term "adhesive overlay" was replaced with "adhesive cover" throughout the labeling.
4. Under **STORAGE AND HANDLING**, the text "CAUTION Federal law prohibits dispensing without prescription." was replaced with "Rx only."
5. The manufacturer information was changed from:  
    Manufactured by  
    Alza Corporation, Palo Alto California 94304  
    Distributed by  
    Boehringer Ingelheim Pharmaceuticals, Inc.  
    Ridgefield, CT 06877  
    Licensed from  
    Boehringer Ingelheim International GmbH  
    U.S. Patent No 4,201,211 Printed in U.S.A.  
    Revised 8/96 830892

To:

Manufactured by:  
ALZA Corporation, Mountain View, CA 94043 USA  
Distributed by:  
Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT 06877 USA  
Licensed from:  
Boehringer Ingelheim International GmbH  
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Revised February 2004  
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Patient Instructions

1. Title of the patient brochure was changed from “**HOW TO USE**” to “**PATIENT INSTRUCTIONS.**”
2. The drug name, **Catapres-TTS (clonidine)**, was added to the beginning of the instructions.
3. The word “patch” was edited to “PATCH” throughout the instructions.
4. The word “overlay” was revised to “ADHESIVE COVER” throughout the instructions.
5. Under **General Information**,
  - a. The first paragraph of the instructions was split into two paragraphs.
  - b. The first sentence, second paragraph, was changed from:

However, should the patch begin to separate from the skin, the white, round, adhesive overlay should be applied directly over it to ensure adhesion for seven full days.

To:

The optional white, round, ADHESIVE COVER should be applied directly over the PATCH, should the PATCH begin to separate from the skin. The ADHESIVE COVER ensures that the PATCH sticks to the skin.
  - c. Added Figure 1 at the end of the **General Information** section to depict the shape and placement of the PATCH and ADHESIVE COVER (to be applied over the PATCH, if necessary).
6. Under **How to Apply the CATAPRES-TTS Patch**,
  - a. Figure 2 was added depicting both types of pouches contained in each box (the PATCH with medication and the ADHESIVE COVER for use if the PATCH becomes loose).
  - b. The subsequent Figures 3-6 were renumbered.
  - c. Under Step 5, the text “with the red and orange colors” was added to read:

5) Select the pouch with the red and orange colors labeled CATAPRES-TTS (clonidine) and open it as illustrated in Figure 3.
  - d. Figure 4, depicting the removal of the clear plastic protective backing from the PATCH was moved from Step 5 and added to Step 6.
  - e. Figure 5, depicting application of the PATCH on the prepared skin was moved from Step 8 to Step 7.
  - f. Step 8, first sentence, the word “Next” was replaced with “After one” to read:

8) After one week, remove the old PATCH and discard it (refer to **Instructions for Disposal**).
7. The text “**What to do if your Catapres-TTS PATCH becomes loose while wearing:**” was added after Step 8.
8. Under the **How to Apply the ADHESIVE COVER** section,
  - a. Under **Note**., the texts “**does not contain any drug**”, “**only**”, and “that it sticks to the skin” were added to read:

**Note:** The white, round ADHESIVE COVER **does not contain any drug** and should not be used alone. The COVER should be applied directly over the CATAPRES-TTS Patch **only** if the PATCH begins to separate from the skin, thereby ensuring that it sticks to the skin for seven full days.
  - b. Step 3, the word “it” was replaced with “the plain white” to read:

3) Take the white, round, ADHESIVE COVER (Figure 6) from the plain white pouch and remove the paper liner backing from the COVER.
  - c. Step 4, the text “round, white” was added to read:

4) Carefully center the round, white ADHESIVE COVER over the square, tan CATAPRES-TTS PATCH and apply firm pressure, especially around the edges in contact with the skin.
9. Under **Instructions for Disposal**, the precautionary statement “**KEEP OUT OF REACH OF CHILDREN**” was revised with un-bolded, lower case letters.
10. The manufacturer information was revised as described above for the Package Insert.

We have completed our review of this supplemental new drug application, as amended, and it is approved effective on the date of this letter, for use as recommended in the electronic final printed labeling (FPL) submitted on February 27, 2004.

In addition, under the PATIENT INSTRUCTIONS/ Instructions for Disposal, we request that you retain the capitalized, bold lettering for the statement, “**KEEP OUT OF REACH OF CHILDREN.**”

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call:

Mr. Daryl Allis  
Regulatory Health Project Manager  
(301) 594-5309

Sincerely,

*{See appended electronic signature page}*

Norman Stockbridge, M.D., Ph.D.  
Acting Director  
Division of Cardio-Renal Drug Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

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/s/

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Norman Stockbridge  
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