KADIAN® Corrective Information Rollout

Training Class: August 19th, 2010

inVentiv Health

CCSF v Purdue Pharma, et al.
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AL-SF-01424
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Agenda

- Introduction to Actavis
- Introduction to KADIAN®
  - Product description
  - Indication
  - Boxed Warning
- Background
  - DDMAC Warning Letter
- Corrective Action Plan
  - Reaching Consumers
  - Executing the Plan: The Five Steps
- Sample Questions
- Key Contact Information

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Please Note…

- Members of our full-time KADIAN® sales team will already be familiar with some of the information in this presentation
  - Please stay with us!
- For everyone on the line, please feel free to ask questions at any time during the presentation

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Introduction to Actavis

- Actavis is a global generic pharmaceuticals company
  - Currently headquartered in Iceland
  - The 5th largest generic pharmaceuticals company in the world
  - EUR 1.7 billion in sales 2009
  - Products sold in over 96 countries; offices in over 40 countries
  - 10,500 employees worldwide
- In the US, Actavis has:
  - 2 manufacturing facilities
  - 3 R&D centers
  - 1,200 employees
  - 88 Currently Marketed Molecules (Product Families)

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Introduction to KADIAN®

- Actavis acquired KADIAN® from King Pharmaceuticals in December 2008
- KADIAN® Capsules are an extended-release oral formulation of morphine sulfate
- Morphine is an opioid agonist and a Schedule II controlled substance
- The principal action of therapeutic value of morphine is analgesia (i.e. reduction of pain)

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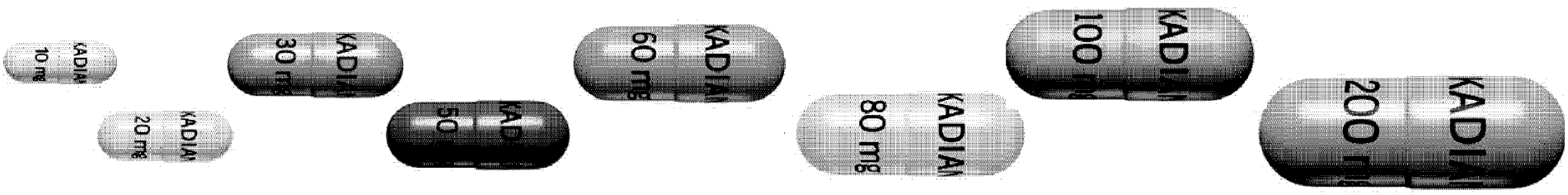
Introduction to KADIAN®

- KADIAN® capsules are supplied in 8 strengths: 10 mg, 20 mg, 30 mg, 50 mg, 60 mg, 80 mg, 100 mg, and 200mg strengths
- Actavis manufactures KADIAN® at its facility in Elizabeth, NJ
- The KADIAN® field sales team is currently comprised of 22 dedicated area business managers and 2 region business directors
  - 2009 sales of KADIAN® were $256M
  - 2009 KADIAN® TRx: 605K



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KADIAN® Indications and Usage

- KADIAN® Capsules are an extended-release oral formulation of morphine sulfate indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time
- **KADIAN® Capsules are NOT intended for use as a prn** analgesic**
- KADIAN® is not indicated for pain in the immediate postoperative period (the first 12-24 hours following surgery), or if the pain is mild or not expected to persist for an extended period of time.
- KADIAN® is only indicated for postoperative use if the patient is already receiving the drug prior to surgery or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time. Physicians should individualize treatment, moving from parenteral to oral analgesics as appropriate.

** This means that KADIAN® capsules are not intended for use on an as needed basis.

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KADIAN® Boxed Warning

WARNING:
KADIAN® contains morphine sulfate, an opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics. KADIAN® can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing KADIAN® in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse or diversion.

KADIAN® capsules are an extended-release oral formulation of morphine sulfate indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

KADIAN® Capsules are NOT for use as a prn analgesic.

KADIAN® 100 mg and 200 mg Capsules ARE FOR USE IN OPIOID-TOLERANT PATIENTS ONLY. Ingestion of these capsules or of the pellets within the capsules may cause fatal respiratory depression when administered to patients not already tolerant to high doses of opioids. KADIAN® CAPSULES ARE TO BE SWALLOWED WHOLE OR THE CONTENTS OF THE CAPSULES SPRINKLED ON APPLE SAUCE. THE PELLETS IN THE CAPSULES ARE NOT TO BE CHEWED, CRUSHED, OR DISSOLVED DUE TO THE RISK OF RAPID RELEASE AND ABSORPTION OF A POTENTIALLY FATAL DOSE OF MORPHINE.

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Background: DDMAC Warning Letter

- Actavis received a Warning Letter from DDMAC relating to KADIAN® promotional materials in February, 2010
- According to the FDA, information in promotional materials used by the KADIAN® sales team and distributed to healthcare professionals (HCPs) and consumers, was false and/or misleading because it:
  - Omitted and minimized the serious risks associated with use of the drug
  - Broadened and failed to present the limitations to the approved indication of the drug
  - Presented unsubstantiated superiority claims, and
  - Presented unsubstantiated effectiveness claims

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Background: DDMAC Warning Letter

- The Warning Letter focused on two promotional items; however other KADIAN® promotional materials being used by the sales team contained similar information
  - Note: the promotional item that is the subject of the Corrective Information Rollout that is being discussed today is the KADIAN® Co-pay Assistance Program Brochure. For your reference:
    - The co-pay program provides up to $50 toward a patient's co-pay or out-of-pocket cost for their monthly KADIAN® prescriptions
    - Co-pay cards, which must be presented to the pharmacy when a prescription for KADIAN® is filled, were spot-glued to a brochure, which was the subject of the Warning Letter
    - Following receipt of the Warning Letter, co-pay cards were separated from the brochure and, along with a PI, continue to be available to patients

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Corrective Action Plan

- Following a lengthy dialogue, Actavis and the FDA recently reached agreement on a plan for providing corrective information to HCPs and Consumers who may have been exposed to the promotional materials cited in the FDA letter
  - This plan involves distribution of "Dear HCP" and "Dear Consumer" letters to the affected audience
    - The letters correct and clarify the statements and representations that, according to the FDA, were made in error
  - The focus of today's training meeting is the rollout of the "Dear Consumer" corrective information letters

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Corrective Action Plan: Reaching Consumers

- To reach consumers who may have been exposed to the co-pay brochure, copies of a "Dear Consumer" letter will be made available to KADIAN® patients through HCP offices and a limited number of pharmacies
- Actavis has committed to the FDA that they will physically visit all affected HCP and pharmacy locations to set up a stand with 25 copies of the "Dear Consumer" letter
  - This is where you come in!

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Corrective Action Plan Execution: The Five Steps

- Step One: Physically visit all affected locations
- Step Two: Communicate purpose of visit along with key messages concerning the Corrective Information
- Step Three: Set up the display stand and copies of the “Dear Consumer” letter
- Step Four: Make a record of the visit
- Step Five: Answer questions relating to the Corrective Information

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Step One: Visit all Locations

- Approximately 8,730 HCP locations and 535 pharmacies are involved
- The full-time KADIAN® sales team will distribute the corrective information to their HCP targets
  - Approximately 2,000 HCPs at 1,635 locations
- The temporary KADIAN® team will call on all other HCP and pharmacy locations
  - Approximately 7,100 HCP locations
  - Approximately 535 pharmacy locations
- Territory lists and maps will be provided to facilitate territory planning
  - inVentiv will provide more details regarding territory planning and logistics

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Step Two: Communicate Key Messages

- HCP office and pharmacy calls are being made on Actavis' behalf
- Actavis is the manufacturer of KADIAN®
- Early in 2010, Actavis received a Warning Letter from DDMAC relating to KADIAN® promotional materials
  - IMPORTANT: The product itself was not the subject of the Warning Letter
- According to the FDA, information in the KADIAN® Co-pay Assistance Program brochure was false and/or misleading because it:
  - (1) left out and minimized serious risks associated with KADIAN®;
  - (2) claimed KADIAN® was approved by FDA for conditions it is not approved for; and
  - (3) presented unsupported claims about how well KADIAN® works

Step Two: Communicate Key Messages

- As a result, the FDA has asked Actavis to make available important correction of drug information regarding KADIAN® to all patients/consumers who may have been exposed to the Co-Pay Assistance Program brochure
  - This information is presented in the form of a “Dear Consumer” letter

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Step Two: Communicate Key Messages

- The "Dear Consumer" letter addresses the FDA's concerns about the statements and representations that were made about KADIAN® in the brochure
  - The full product indication is provided to clarify that KADIAN® is indicated to treat only certain types of pain
  - Full disclosure of the serious risks associated with the use of KADIAN® is provided, including boxed warning information, as well as contraindications and side effects to ensure patients are fully informed
  - Clarification regarding the effectiveness of KADIAN and the impact that it has on a patient's life is made

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Step Two: Communicate Key Messages

- The FDA has asked that this important corrective drug information regarding KADIAN® be prominently displayed in the patient waiting area so that all patients have ready access to the information contained in the letter
- Further, the FDA has asked that this information be made available to patients for a 90 day period
- An Actavis representative will be contacting each office/pharmacy once per month to ensure that sufficient quantities of the letter are available to patients during this 90-day period
  - Note: telesales will be conducting follow-up calls at 30 day intervals
- If additional copies are required prior to the follow-up calls, instruct HCP offices and pharmacies to call 1-800-249-4650 to request that additional copies be sent

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Step Two: Summary of Key Messages

- The FDA has requested that this information be made available to patients
- Concerns cited in the Warning Letter pertained to KADIAN® promotional materials, not to the product itself
- The "Dear Consumer" letter corrects and clarifies the statements and representations that were made about KADIAN® in the promotional material
- The FDA requires that this information be made available to patients for 90 days
- Call 1-800-249-4650 if additional copies of the letter are required

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Tips: Who Should You Talk To?

In a Healthcare Professional's Office

- Ask to speak with the prescribing physician
- If unavailable, ask to speak to a PA or NP
- If unavailable, speak with another member of the staff or office manager

In a Pharmacy

- Ask to speak with the pharmacist on duty
- If unavailable, ask to speak with the pharmacy technician or other pharmacy personnel

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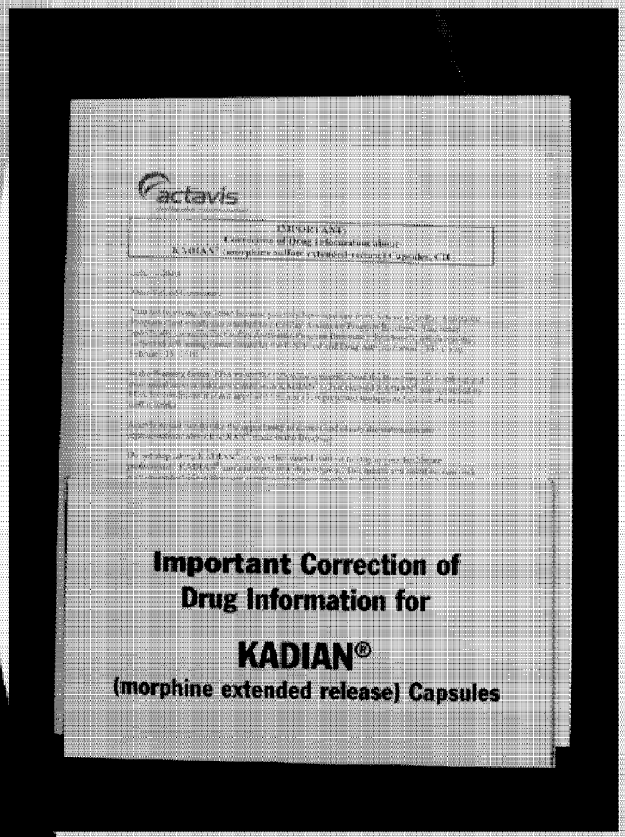
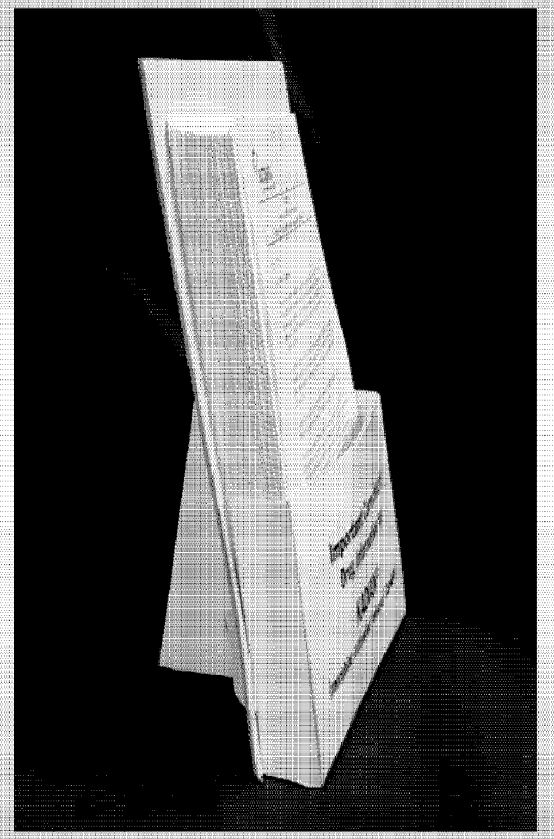
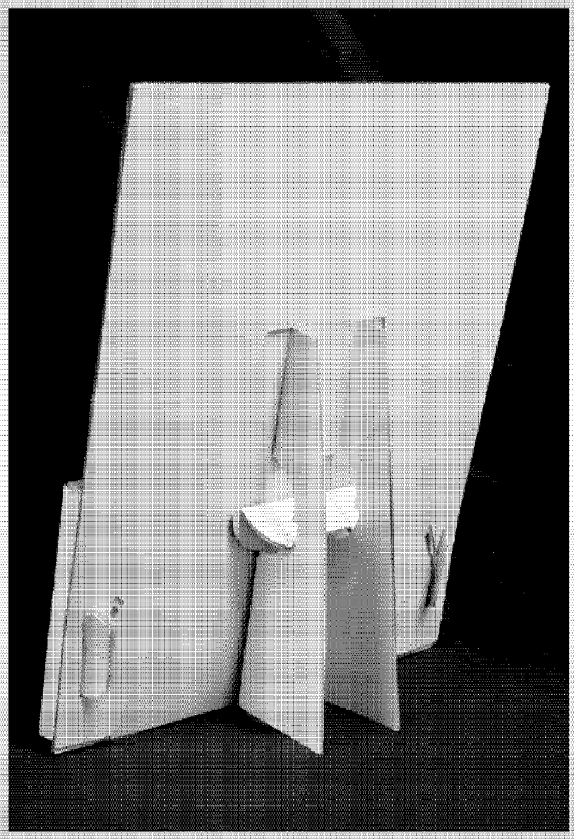
Step Three: Set up the Information







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KADIAN®

Morphine Sulfate Extended-Release Capsules

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Tips: Where Should the Information be Displayed?

- The FDA has requested that the information be displayed in the patient waiting area
- If the office does not want to display the information in the waiting area, ask if there is somewhere else in the office that they would consider displaying the information

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Step Four: Make a Record of the Visit

- A KADIAN® Corrective Information Call Form must be completed for each location in your call plan
  - HCP/Pharmacy name and address information will need to be legibly printed on the forms
  - Complete information relating to whether or not party at location agreed to display the materials or refused
  - An authorized signature must be obtained along with the name and contact number of someone to be contacted for follow-up calls
- Additional information regarding completion of the Call Form and logistics will be provided by inVentiv later on during this training session

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Step Five: Answer Questions

- Only answer questions relating to the Warning Letter and the Corrective Information
  - This is not a sales call!
- Refer all questions relating to KADIAN® to Medical Affairs at 1-888-496-3082
- Refer all requests for KADIAN® Co-pay Assistance Cards to Triple I help desk at 1-877-637-4629

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Sample Question #1

- Q: Is it safe for patients to be taking KADIAN®?
- A: The subject of the Warning Letter was the product's promotional materials, not the product itself.

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Sample Question #2

- Q: Should patients stop taking KADIAN®?
- A: No. This Corrective Action is being taken due to the FDA's response to KADIAN® promotional materials, not the product.

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Sample Question #3

- Q: Have any patients been adversely affected as a result of the information that was contained in the co-pay card brochure?
- A: The subject of the Warning Letter was the product's promotional materials, not the product itself.

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Sample Question #4

- Q: Do you have co-pay cards available today?
- A: Please contact the KADIAN® Co-Pay Card Help Desk at 1-877-637-4629 to request co-pay cards for your office.

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Sample Questions: Overview

In general, your response to questions should be focused on the corrective action. If asked anything about KADIAN®, please remember to respond that:

- The subject of the Warning Letter was the product's promotional materials, not the product itself.
- Any additional questions should be directed to Medical Affairs at 1-888-496-3082

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Key Contact Information

- For additional copies of the "Dear Consumer" letter
  - 1-800-249-4650
- KADIAN® Medical Affairs
  - 1-888-496-3082
- KADIAN® Co-Pay Assistance Program: Triple I Help Desk
  - 1-877-637-4629
- These numbers will be printed on the Call Forms for your reference

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