



FILE COPY

February 16, 2009



UPS OVERNIGHT COURIER

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

**RE: NDA # 20-616 KADIAN® (morphine sulfate extended-release) Capsules,
10 mg, 20 mg, 30 mg, 50 mg, 60 mg, 80 mg, 100 mg, and 200 mg**

Dear Sir/Madam:

Actavis Elizabeth LLC is hereby submitting, in duplicate, the following promotional material(s), for KADIAN® (morphine sulfate extended-release) Capsules:

Co-pay Assistance Program
Job Code: KAD200901

If you have any questions relating to this submission, please do not hesitate to contact the undersigned at (908) 659-3017.

Sincerely,

ACTAVIS ELIZABETH LLC

Lucy Gary
Manager, Labeling, Regulatory Affairs

/cg
Enclosures

Actavis Elizabeth LLC | 200 Elmora Avenue | United States | t :908) 527 4110 | e : actavis@actavis.com
Actavis Mid-Atlantic LLC | Elizabeth, NJ 07207 | f :908) 659 2250 | w : www.actavis.com



TRANSMITTAL OF ADVERTISEMENTS AND PROMOTIONAL LABELING FOR DRUGS AND BIOLOGICS FOR HUMAN USE	1. DATE SUBMITTED 02/16/2009	3. NDA/ANDA/AADA OR BLA/PLA/PMA Number: Single product <input checked="" type="checkbox"/> Multiple products <input type="checkbox"/> For multiple products, submit completed form and specimen of advertising/promotional materials to one application of choice, and attach separate sheet addressing items 3-5 for remainder of products. Refer to No. 3 on instruction sheet.
	2. LABEL REVIEW NO. (Biologics)	

NOTE: Form 2253 is required by law. Reports are required for approved NDAs and ANDAs (21 CFR 314.81)

4. PROPRIETARY NAME KADIAN	5. ESTABLISHED NAME Morphine Sulfate Extended-Release Capsules Prod. Code No. N/A
6. PACKAGE INSERT DATE and ID NO. (Latest final printed labeling) Rev. January 2008 Part# 40-9068	7. MANUFACTURER NAME: License No. (Biologics)

FDA/CBER USE ONLY

REVIEWED BY	DATE	RETURNED BY	DATE

8. ADVERTISEMENT / PROMOTIONAL LABELING MATERIALS

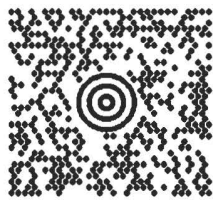
Please check only one: Professional Consumer

Material Type (use FDA codes) a.	Dissemination/ Publication Date b.	Applicant's Material ID Code and/or description c.	Previous review No. if applicable / date (PLA Submissions) d.	COMMENTS:
PLT	January 2009	KADIAN Co-Pay Assistance Program	N/A	Add Continuation Page

9. TYPED NAME AND TITLE OF RESPONSIBLE OFFICIAL OR AGENT Lucy Gary Manager, Labeling, Regulatory Affairs	10. SIGNATURE OF RESPONSIBLE OFFICIAL
11. APPLICANT'S RETURN ADDRESS 200 Elmora Avenue Elizabeth, NJ 07207 USA	12. RESPONSIBLE OFFICIAL'S a. PHONE NO. (908) 659-3017 b. FAX NO. (909) 659-2250
	13. FOR CBER PRODUCTS ONLY: (Check one) <input type="checkbox"/> Part I/Draft <input type="checkbox"/> Part II/Final

FROM:
CARLA HEDRICK
(908) 659-9100
ACTAVIS ELIZABETH LLC
200 ELMORA AVENUE
ELIZABETH NJ 07202-1106

2 LBS 1 OF 1
DWT: 13,11,2



MD 207 9-59



SHIP TO:

FOOD AND DRUG ADMINISTRATION
CDER
DIV OF DRUG MARKETING, ADVERTISING
5901-B AMMENDALE ROAD
BELTSVILLE MD 20705-1266

UPS NEXT DAY AIR

TRACKING #: 1Z 062 077 01 4564 1648

1



REF 1:20-616

BILLING: P/P

WS 11 0 14 HP LaserJet 8 87 0A 01/2009

Fold here and place in label pouch



Delivery Notification

Dear Customer,

This is in response to your request for delivery information concerning the shipment listed below.

Tracking Number: 1Z 062 077 01 4564 164 8
Reference Number(s): 20-616
Service: NEXT DAY AIR
Weight: 2.00 Lbs
Shipped/Billed On: 02/16/2009
Delivered On: 02/17/2009 9:05 A.M.
Delivered To: 5901B AMMENDALE RD
BELTSVILLE, MD, US 20705
Signed By: MANG
Location: RECEIVER

Thank you for giving us this opportunity to serve you.

Sincerely,
UPS

Tracking results provided by UPS: 02/17/2009 4:03 P.M. ET

<https://wwwapps.ups.com/WebTracking/processPOD?lineData=LAUREL%5EKB%5EUS...> 2/17/2009

KADIAN[®] CO-PAY ASSISTANCE Program

Save up to **\$50**
toward each prescription of KADIAN[®]
See details inside.

Good for up to
\$600
for 12 months



For questions about this program, please call the Help Desk at 1-877-637-4629.
Pharmacists only: For claim-related questions, please call Therapy First at 1-800-422-5604

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.

Safety considerations:

KADIAN® (morphine sulfate extended-release)
Capsules contain 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.

Serious adverse reactions that may be associated with KADIAN® therapy in clinical use are those observed with other oral opioid analgesics and include: respiratory depression, respiratory arrest, circulatory depression, cardiac arrest, hypotension, and/or shock.

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.

For further information about
KADIAN™, please visit
www.KADIAN.com
or call 1-877-637-4629.

*Please see accompanying
complete Prescribing Information.*

KADIAN™ is a registered trademark of Actavis.



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KAD200901 January 2009
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January 29, 2008

Re: KADIAN® CO-PAY ASSISTANCE PROGRAM

Dear Health Care Provider:

As you may know, KADIAN® was recently acquired by Actavis Group. Actavis has a long history with KADIAN®; the product was originally developed and commercially launched from Actavis' facility in Elizabeth, New Jersey. KADIAN® has been manufactured at this site ever since, and Actavis will continue to deliver the same quality and reliability that you have come to expect from the product.

This acquisition is the latest step in Actavis' strategy to expand its specialty drug portfolio and is in-line with our focus on bringing complex controlled-release products to the marketplace. We are committed to providing you and your patients with important, innovative products such as KADIAN®.

As part of this commitment, Actavis is pleased to announce the continuation of the KADIAN® Co-pay Assistance program. This program is designed to provide your patients with savings of up to \$50 off their co-pay or out-of-pocket expenses for up to 12 prescriptions of KADIAN®. Included in this mailing, you will find 10 co-pay cards and information pertaining to the use of the cards. We have also included complete prescribing information and a re-order form in the event you would like to receive additional co-pay cards.

I appreciate your patience during this recent transition and apologize for any inconvenience you or your patients may have experienced while we updated the Co-pay Assistance Program. If you have any questions, please do not hesitate to contact me or our KADIAN® Co-pay assistance support line at 1-877-637-4629.

Sincerely Yours,

Doug Boothe
Chief Executive Officer
Actavis Inc.

Actavis Inc.

Actavis US Headquarters
60 Columbia Road, Building B
Morristown, NJ 07960

☎ 973 993 4501
☎ 973-993-4303

www.actavis.com

Why is pain management important?

Pain management is a large part of your overall health care plan. Many Americans suffer from chronic or ongoing pain. It can cause you to miss work and can even keep you from enjoying life. If left untreated, pain can place stress on your body and your mental health. Managing your pain the right way begins by talking to your healthcare provider. Discover the cause of your pain by taking note of what makes your pain start and what makes it worse.

What is chronic pain?

Chronic pain is ongoing and can last longer than 6 months. Chronic pain can be mild or severe. It can be inconvenient and can keep you from your daily tasks.

How can I treat my chronic pain?

To help manage your pain, your healthcare provider will determine what level of pain control you need. Depending on what kind of pain you have and how it affects your life, your healthcare provider will choose a drug that works just for you.

Please see accompanying complete Prescribing Information.

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.

Safety considerations:

KADIAN® (morphine sulfate extended-release) Capsules contain 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.

Serious adverse reactions that may be associated with KADIAN® therapy in clinical use are those observed with other oral opioid analgesics and include: respiratory depression, respiratory arrest, circulatory depression, cardiac arrest, hypotension, and/or shock.

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.

For further information about KADIAN®, please visit www.KADIAN.com or call 1-877-637-4629.

Please see accompanying complete Prescribing Information.

KADIAN® is a registered trademark of Actavis.



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KAD200901 January 2009
Printed in USA

KADIAN®

(Morphine Sulfate Extended-Release Capsules)

100 mg and 200 mg capsules

save up to **\$50** each month toward your KADIAN® prescription.

Please see accompanying complete Prescribing Information.

Expiration date: 12-31-09

KADIAN®
CO-PAY ASSISTANCE Program

Save up to **\$50**
toward each prescription of KADIAN®
See details inside.

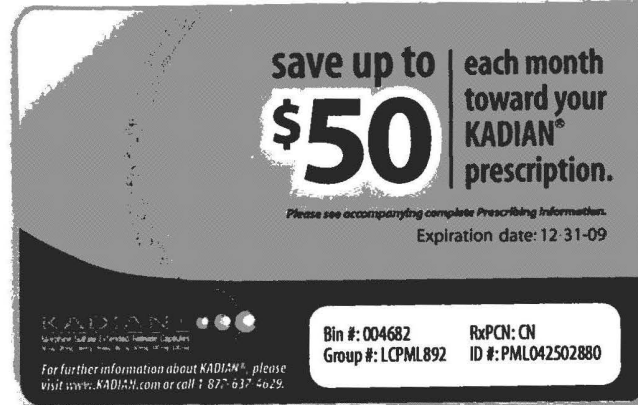
Good for up to
\$600
for 12 months

KADIAN®
Morphine Sulfate Extended-Release Capsules
100 mg and 200 mg capsules

For questions about this program, please call the Help Desk at 1-877-637-4629.
Pharmacists only. For claim-related questions, please call *Therapy First* at 1-800-422-5604.

KADIAN®

CO-PAY ASSISTANCE Program



The KADIAN® (morphine sulfate extended-release) Capsules Co-pay Assistance Program

The KADIAN® Co-pay Assistance Program provides up to \$50 toward your co-pay or out-of-pocket cost for your KADIAN® prescriptions. Please see your pharmacist to help you determine your monthly savings amount.

Present this card with your KADIAN® prescription and insurance card, if applicable. You can use the same card with every prescription of KADIAN® until the expiration date that's printed on the card.

Terms and Conditions: Valid only at participating retail pharmacies in the US and Puerto Rico. Not valid through mail-order pharmacies. This offer is limited up to one savings per prescription. Card is limited to 1 per patient for the life of the program and is not transferable. This coupon card is not valid for prescriptions purchased under Medicaid, Medicare, federal or state programs (including state prescription drug programs, private indemnity or HMO Insurance plans which reimburse you for the entire cost of your prescription drugs). This offer is not valid in Massachusetts, except for cash paying patients. Void where prohibited by law, taxed or restricted. Actavis reserves the right to rescind, revoke or amend this offer without notice at any time.

Please see accompanying complete Prescribing Information.

KADIAN® (morphine sulfate extended-release) Capsules \$50 Multi-Use Coupon FAQ Sheet

Question: Do I have to call an 800 number or go onto the Internet to activate the card?

Answer: No. The card is already active. Simply present the card with a valid 30-day prescription for KADIAN® capsules to your pharmacist. You can request a card at www.kadian.com.

Question: Do I have to present the card every time?

Answer: Present this card to your pharmacist every time you fill your Kadian® prescription.

Question: What if I have an issue with redeeming the \$50 multi-use coupon card at the pharmacy?

Answer: You must contact the Help Desk at 1-877-637-4629 to address this issue.

Question: How long do I have to wait before I can use the card for the next prescription?

Answer: You can re-use the card after 23 days of the last fill date.

Question: Can I use the card with mail order programs?

Answer: No. You can not use this card with participating mail order pharmacies. To find a local pharmacy that participates, please contact the Help Desk at 1-877-637-4629.

Question: Can I use the \$50 multi-use coupon card after the expiration date?

Answer: No. The card cannot be used past the expiration date.

If you have any questions on how to use your Co-Pay Assistance Card, please call 1-877-637-4629.

10 9068

KADIAN[®]
Morphine Sulfate
Extended-Release Capsules



Revised — January 2008

KADIAN[®] (morphine sulfate extended-release) Capsules

other tranquilizers, and alcohol because respiratory depression, hypotension, and profound sedation or coma may result.

Gastrointestinal Obstruction

KADIAN[®] should not be given to patients with gastrointestinal obstruction, particularly paralytic ileus, as there is a risk of the product remaining in the stomach for an extended period and the subsequent release of a bolus of morphine when normal gut motility is restored. As with other solid morphine formulations diarrhea may reduce morphine absorption.

Other

Although extremely rare, cases of anaphylaxis have been reported.

PRECAUTIONS

General

KADIAN[®] is intended for use in patients who require continuous, around-the-clock opioid analgesia for an extended period of time. As with any potent opioid, it is critical to adjust the dosing regimen for KADIAN[®] for each patient. Patients who report the patient's ~~excessive pain to the prescriber~~ severe, even fatal consequences.

4. Patients should be advised that the dose of KADIAN[®] should not be adjusted without consulting the prescribing health care provider.
5. Patients should be advised to report episodes of breakthrough pain and adverse experiences occurring during therapy. Individualization of dosage is essential to make optimal use of this medication.
6. Patients should be advised that KADIAN[®] may impair mental and/or physical ability required for the performance of potentially hazardous tasks (e.g., driving, operating machinery). Patients started on KADIAN[®] or whose dose has been changed should refrain from dangerous activity until it is established that they are not adversely affected.
7. Patients should be advised that KADIAN[®] should not be taken with alcohol or other CNS depressants (sleeping medication, tranquilizers) except by the orders of the prescribing healthcare provider because dangerous additive effects may occur resulting in serious injury or death.
8. Women of childbearing potential who become or are planning to become pregnant should consult their prescribing healthcare provider prior to initiating or continuing therapy with KADIAN[®].

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FOR PROTECTIVE ORDER

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