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MLG CSR 11976
11/18/2021
Robin Hagy
Exh. 8

August 3, 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:

KADIAN "...When you can prescribe the benefits..."
Material Code: KAD18D0231

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

EXHIBIT 10

Hagy
11/13/19

Reported by: Emily
Samelson, CSR 14043

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**PLAINTIFFS TRIAL
EXHIBIT
P-21964_00001**

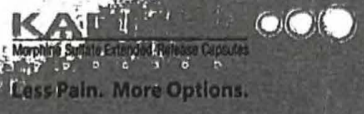
CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

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P-21964 _ 0001

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

**...When you can prescribe the benefits
of KADIAN[®] capsules?**



ALLERGAN_MDL_01290414

Prescribe

WARNING:
KADIAN® con
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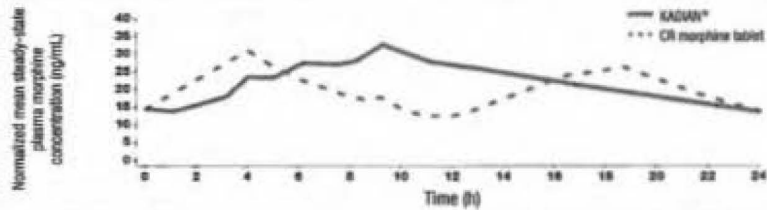


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KADIBD0231 Printed in the USA

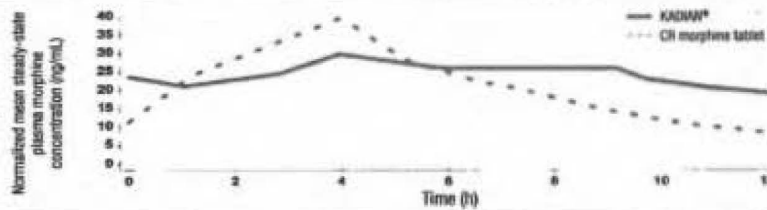
Fewer peaks and valleys

Smooth steady-state plasma levels compared with controlled-release (CR) morphine tablets q12h and q24h¹

Pharmacokinetics of ONCE-DAILY KADIAN® vs twice-daily CR morphine tablets over 24 hours¹



Pharmacokinetics of TWICE-DAILY KADIAN® vs twice-daily CR morphine tablets over 12 hours¹

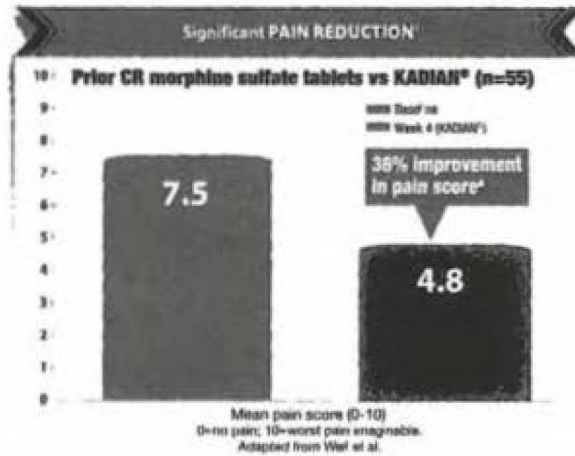


Allow for less breakthrough pain and more consistent pain relief for patients²

Please see accompanying complete Prescribing information.

Better pain control and improved sleep scores

Improved pain control and sleep scores in patients treated with KADIAN® who were previously on CR morphine tablets^{3*}



¹Both significant at $P < 0.001$. Baseline vs week 4 per protocol population, post hoc analysis.

Allow patients to live with less pain and get adequate rest with less medication²

²In a subanalysis of a randomized, open-label, blinded endpoint study of patients previously taking CR morphine tablets and switched to KADIAN® capsules.





















Please see accompanying complete Prescribing Information.





Fewer barriers to prescribing

The unique dosing flexibility of KADIAN gives you more options with **amorphine**^{1,4,5}

KADIAN*	 10 mg	 20 mg	 30 mg	 40 mg	 60 mg	 80 mg	 100 mg	 120 mg
MS Contin*	 10 mg	 20 mg	 30 mg	 60 mg	 100 mg	 200 mg		
AVINZA*	 20 mg	 40 mg	 60 mg	 75 mg	 90 mg	 120 mg		

Capsules and tablets are not shown or actual size.

- No immediate-release (IR) component
- No ceiling dose—contains no acetaminophen, ibuprofen, or fumaric acid¹
- Allows for titration in increments of 10 mg, with a low dose of 10 mg¹

Allow individualization and customization of a patient's pain treatment

Please see accompanying complete Prescribing Information.



**Why settle for generic
MS Contin[®] tablets...**

Prescribe KADIAN®—Less pain for your patients. More options for you.

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.

Safety considerations:

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, apnea, circulatory depression, cardiac arrest, hypotension, and/or shock.

References: 1. KADIAN® [prescribing information]. Morristown, NJ: Actavis Elizabeth LLC; 2. Gourlay GK, Cherry DA, Onley MM, et al. Pharmacokinetics and pharmacodynamics of twenty-four-hourly Kapanol compared to twelve-hourly MS Contin in the treatment of severe cancer pain. *Pain*. 1997; 69(1):295-312; 3. Weil A, Nicholson B, Ross E, Sasaki J. Patients with chronic, non-malignant, moderate/severe pain can be successfully switched from other sustained-release morphine or oxycodone compounds to KADIAN® (morphine sulfate sustained release capsules); the KRONUS-MSP trial. Poster presented at: American Pain Society 23rd Annual Scientific Meeting, May 6-9, 2004, Vancouver, BC, Canada; 4. AVINZA® [prescribing information]. Bristol, TN: King Pharmaceuticals Inc; April 2008; 5. MS Contin® [prescribing information]. Stamford, CT: Purdue Pharma LP; August 2007.

For further information, please visit www.KADIAN.com or call 1-888-496-3082.

Please see accompanying complete Prescribing Information.



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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, taking into account the patient's prior analgesic treatment experience. Although it is clearly