From: Jennifer Altier < jaltier2001@yahoo.com>

To: bdesantis@tmshealth.com

**CC:** Nathalie Leitch **Sent:** 9/9/2011 2:37:23 AM

Subject: New TMS Script/Letters for KADIAN

Attachments: TMS Generic Letter #1.docx; TMS Generic Letter #2.doc.docx; TMS Generic Telescript

clean.docx; TMS Generic Telescript.docx

Betty,

The attached script and follow-up letters have been approved. I've attached a clean version of the script as well as one that highlights the changes made to the current script.

The flyers that will accompany the letters are awaiting final regulatory approval and should be available to ship to you next week. Please review the script with your team - I was hoping we could schedule a training call next week so that we can roll-out the script on Monday, 9/19. Please let me know what day and time would work for you.

If you have any questions please let me know.

Thanks, Jennifer

PLAINTIFF TRIAL EXHIBIT
P-22197\_00001

ACTAVIS LOGO
Date
Dr First Name, Last name
Attn:Address1 Address2 City, State, Zip
Dear:
Thank you for taking the time to speak with me regarding $KADIAN^{\circledast}$ (morphine sulfate extended-release) Capsules.
As mentioned, enclosed please find information on how you can help your patients greatly reduce the amount they pay for their KADIAN® prescriptions. Your request for KADIAN® Prescription Co-Pay Cards will be fulfilled under separate cover. Please be aware that we also provide a Patient Assistance Program at 888-206-9743 for your patients who qualify. We will be following up with you in the near future to ensure that your needs and the needs of your patients continue to be met.
Thank you again for your continuing support. If you have any questions or require additional information, please feel free to contact us at 800-216-1162 or visit our website at <a href="https://www.KADIAN.com">www.KADIAN.com</a> .
Best regards,
KADIAN® Sales Representative
Enclosed: Co-Pay Costs Flashcard
KADI1161(1)

ACTAVIS LOGO
Date
Dr First Name, Last name
Attn:Address1 Address2 City, State, Zip
Dear:
Thank you for taking the time to speak with me regarding $KADIAN^{\mathbb{R}}$ (morphine sulfate extended-release) Capsules.
As mentioned, enclosed please find information on how you can help your patients greatly reduce the amount they pay for their KADIAN $^{\otimes}$ prescriptions. We understand that you do not have a need for KADIAN $^{\otimes}$ Prescription Co-pay cards. Please be aware that we do provide a Patient Assistance Program at 888-206-9743 for your patients who qualify. We will be following up with you in the near future to ensure that your needs and the needs of your patients continue to be met.
Thank you again for your continuing support. If you have any questions or require additional information, please feel free to contact us at 800-216-1162 or visit our website at <a href="https://www.KADIAN.com">www.KADIAN.com</a> .
Best regards,
KADIAN® Sales Representative
Enclosed: Co-Pay Costs Flashcard
KADI1161(2)

### TMS Health Telesales Script Rev 8/31/11

# Call Introduction for KADIAN® (morphine sulfate extended release) Capsules CII:

IMPORTANT NOTE: If at any time during this call a medical concern is raised, please remind the physician to contact Actavis Medical Affairs at 1-888-496-3082.

Gatekeeper Opening
Good morning/afternoon. This is I am calling on behalf of Actavis. May I ask to whom I am speaking? (Record the name of the Gatekeeper). I would like to speak with Dr regarding of the price of long acting opioids. (May I speak with him/her?)
(If "YES" proceed to the PHYSICIAN SCRIPT/OPENING)
(If doctor is unavailable, follow steps below inserting where appropriate the gatekeeper and doctor's name)
1. May I hold for the possibility of reaching the doctor between patients? I will respect his/her time and be brief. I don't mind holding if that is okay with you. (If "Yes," proceed to PHYSICIAN SCRIPT/OPENING)
If it is not possible to hold
2. I really appreciate your help. I believe Dr will be interested in hearing about the cost of long acting opioids for your patients. I would like to make an appointment to speak to him/her at a time that is convenient – perhaps early morning/around noon hour or later in the evening? (If "Yes," schedule call back time.) Thank you for your help. I look forward to speaking with Dr at that time.
If response is "There is no good time to speak to the doctor" or "He/she won't speak to you"
3. I understand it is difficult to reach him/her while seeing patients. May I leave my name and number and a message so he/she may contact me at his/her convenience?
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### If response is "He/she won't call you either"

4. Is there a nurse practitioner or physician's assistant in the office that I may be able to speak with? (If "Yes," record name and proceed to PHYSICIAN SCRIPT/OPENING)

	esponse is "No, he/she won't speak to you either" or "There is no NP or in this office"
Dr <b>SCI</b>	Perhaps the nurse or Medical Assistant that works most closely with ? (Record Nurse's name and proceed to NURSE RIPT/OPENING, make an appointment or leave toll-free number if tessary)
	t any point in the conversation you are asked to "fax or mail the ormation"
1	We would be glad to mail the doctor some information regarding the cost of long acting opioids to patients. May I confirm the doctor's mailing address? (Verify full name, business name, mailing address.) Thank you. When can I follow up on the information with Dr? (If requested to send info to the NP/PA, Nurse or MA they should get their name for follow up as well).
NU	RSE SCRIPT/OPENING
ACT	od morning/afternoon. My name is I am calling on behalf of avis. Is this, the nurse for Dr? (Ask and record name ot already secured) Thank you for taking my call; I will be brief.
pati you for a	regarding the cost of long acting opioids to ents. When a generic morphine sulfate is prescribed, I presume that cost to r patients is a major factor in that decision. I'm calling today to explain why a majority of your managed care patients, KADIAN can be a less expensive on than a generic product.
\$6.0 for t goo	2010, the average cost to patients of all generic prescription products was 206. 87% of KADIAN patients with managed care coverage pay less than \$50 their prescription. If they use the KADIAN co-pay assistance card, which is 30 for the patient's co-pay, they would actually pay \$0 for their DIAN prescription.
and	buld be happy to send you more information about the KADIAN co-pay card how the majority of your managed care patients can pay \$0 for their scription.NOTE: If asked, the co-pay card is not valid for prescriptions
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purchased under Medicaid, Medicare, federal or state drug programs, private indemnity or HMO insurance plans which reimburse patients for the entire cost of prescription drugs. The card is not valid in Massachusetts, except for cash paying patients.

Should your physician prescribe KADIAN®, I would like to make sure that the doctor is aware of this information. Would it be possible to speak to Dr. at this time? (If "Yes," proceed to PHYSICIAN SCRIPT/OPENING)

If doctor is unavailable, follow same steps as with Gatekeeper).

### PHYSICIAN SCRIPT/OPENING

Good morning/afternoon Dr.\_\_\_\_\_. Thank you for taking my call, I will be brief. My name is \_\_\_\_\_. I am calling on behalf of Actavis regarding KADIAN® (morphine sulfate extended release) Capsules.

Today I'd like to speak to you about the price of long acting opioids. When a generic morphine sulfate is prescribed, I presume that cost to your patients is a major factor in that decision. I'm calling today to explain why for a majority of your managed care patients, KADIAN can be a less expensive option than a generic product.

In 2010, the average cost to patients of all generic prescription products was \$6.06. 87% of KADIAN patients with managed care coverage pay less than \$50 for their prescription. If they use the KADIAN co-pay assistance card, which is good for the first \$50 of the patient's co-pay, they would actually pay \$0 for their KADIAN prescription.

I would be happy to send you more information about the KADIAN co-pay card and how the majority of your managed care patients can pay \$0 for their prescription. Would you like me to mail a copy of this information to your office? (If "Yes" please take contact name and fax number and continue with script. If "No", continue with script).

NOTE: If asked, the co-pay card is not valid for prescriptions purchased under Medicaid, Medicare, federal or state drug programs, private indemnity or HMO insurance plans which reimburse patients for the entire cost of prescription drugs. The card is not valid in Massachusetts, except for cash paying patients.

Note: If you are cut-off at any time during the discussion of KADIAN's full indication, remind the HCP that KADIAN® is only appropriate for use in a very limited patient population who experience persistent moderate to severe pain. Also inform the HCP that following the call, you will be

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### sending a copy of the KADIAN® PI which contains the full indication and risk information for their reference.

Note: If you are asked at any time for the status of KADIAN® on plans not on your list, please let the doctor/office staff know that you can find out and get back to them later. You may remind the doctor/office staff that KADIAN® has excellent managed care coverage with most plans at second or third tier; in fact, KADIAN® has formulary coverage for the majority of patients in the top 25 U.S. health plans. If you are asked for the status of another product aside from KADIAN®, please let them know that you do not have access to that information.

As you know, KADIAN® is 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® is also indicated for post-operative use only if the patient was already receiving KADIAN® prior to surgery or if the post-operative pain is expected to be moderate to severe and persist for an extended period of time.

KADIAN® is NOT indicated for pain in the immediate post-operative period (the first 12-24 hours following surgery), of or if the pain is mild or not expected to persist for an extended period of time.

KADIAN® is NOT intended for use as a PRN analgesic.

KADIAN® capsules are to be swallowed whole or the contents sprinkled on applesauce. The pellets in the capsules must not be chewed, crushed, or dissolved due the risk of rapid release and absorption of a potentially fatal dose of morphine.

You also might be interested to know that that Actavis offers a **KADIAN®** CO-PAY ASSISTANCE CARD PROGRAM for your patients. The card provides your patients with up to \$50.00 towards their KADIAN® prescription co-pay or out-of-pocket costs.

How do you decide which medication to prescribe for your patients with chronic pain?

Note: An HCP's response to the above question may give you an opportunity to provide additional information about KADIAN® capsules. When providing additional information or responding to questions, only communicate the most relevant/most appropriate statements from the list below that are responsive to the HCP's question. Do not read the entire list of statements unless all of the information is relevant to the discussion.

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### **ABOUT KADIAN®**

Doctor, as you may recall

- KADIAN® contains morphine as its active ingredient and has a long history of safety and efficacy when used as indicated
- KADIAN® has a well known side effect profile
- KADIAN® provides steady blood levels of morphine sulfate with few peaks and valleys
- KADIAN® is stocked in pharmacies nationwide
- KADIAN® has excellent managed care coverage with most plans at second or third tier; in fact, KADIAN® has formulary coverage for the majority of patients in the top 25 U.S. health plans (source: AIS Directory of Health Plans: 2011, Fingertip Formulary (T2 and T3) and Data on File at Actavis Elizabeth LLC).
- KADIAN® is in a preferred position on many state public aid programs
- KADIAN® has a generous co-pay assistance program. Its' \$50 co-pay card significantly reduces the patient's out-of-pocket expenses
- KADIAN® Co-pay cards can be used 2x per month.
- KADIAN® Co-pay cards have no expiration date.

### **KADIAN® DOSING**

- KADIAN® is available in 8 different strengths and can be titrated in 10mg increments. The availability of these 8 doses provides flexibility in dose selection.
- KADIAN® provides convenience and flexibility with once or twice a day dosing.
- KADIAN® doses can be titrated up every other day.
- KADIAN does not have a ceiling or recommended maximal dose, especially in patients with chronic pain of malignancy. In such cases the total dose of KADIAN should be advanced until the desired therapeutic endpoint is reached or clinically-significant opioid-related adverse reactions intervene.

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Confidential

- KADIAN® has no significant food effect and can be administered without regard to meals for dosing convenience.
- KADIAN® is available as an extended release capsule, but it has 3 modes of administration,
  - o the capsules can be swallowed whole;
  - the contents of the capsule can be sprinkled on a small amount of applesauce at room temperature or cooler; or
  - The pellet contents of the capsule may be administered through a G-tube.
- The capsules are to be swallowed whole or the contents sprinkled on applesauce. The pellets in the capsules must not be chewed, crushed, or dissolved due the risk of rapid release and absorption of a potentially fatal dose of morphine.

Actavis will continue to assist your patients with (1) our Co-pay Assistance Program and (2) our Patient Assistance Program for those patients that cannot afford KADIAN® and qualify.

Do you currently have any KADIAN® Co-Pay Assistance Cards?

How often do you provide your patients with Co-Pay Assistance Cards?

If the HCP uses co-pay cards/ would you like to receive additional co-pay assistance cards?

### **FAIR BALANCE**

Note: If you are unable to complete the discussion of the fair balance information, inform the HCP that a copy of the PI will be sent for the HCP's information and proceed to CLOSE.

As you know, there also are risks associated with the use of KADIAN®.

KADIAN® contains morphine sulfate which is 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®.

Revision Date: August 31, 2011 6 KADI1162 KADIAN® 100mg and 200mg 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® is contraindicated in patients with a known sensitivity to morphine or any of its other ingredients, or in any situation where opioids are contraindicated including patients with respiratory depression acute or severe bronchial asthma or hypercarbia. KADIAN® should not be given to patients with gastrointestinal obstruction, particularly those with or suspected of having paralytic ileus.

KADIAN® may be expected to have additive effects when used with alcohol, other opioids, or drugs that cause central nervous system depression including sedatives, hypnotics, anesthetics, phenothiazines, and other tranquilizers.

Respiratory depression is the chief hazard of all morphine preparations and can occur more frequently in elderly or debilitated patients or in patients who also have other respiratory conditions. The effects may be more exaggerated in patients with head injuries or intracranial lesions.

KADIAN® may cause severe hypotension, orthostatic hypotension, and syncope and should be used with caution in patients with circulatory shock

KADIAN® should be discontinued 24 hours before a scheduled cordotomy or other interruption of pain transmission pathways.

KADIAN® should be used with caution in patients with biliary tract disease, including acute pancreatitis.

KADIAN® may impair the mental and/or physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery.

KADIAN® should only be used in pregnancy if the need for strong opioid analgesia justifies the potential risk to the fetus. KADIAN® is not recommend for use in women during and immediately prior to labor. KADIAN® should not be used in nursing mothers.

KADIAN® has not been studied in patients below the age of 18 years. The range of doses available is not suitable for very young pediatric patients and the apple sauce sprinkling method of dosing is not an appropriate alternative for these patients.

KADIAN® should be dosed cautiously in elderly patients, usually starting at the low end of the dosing range.

Revision Date: August 31, 2011 7 KADI1162 Serious adverse reactions that may be associated with KADIAN® therapy are those observed with other opioid analgesics and include: respiratory depression, respiratory arrest, apnea, circulatory depression, cardiac arrest, hypotension, and/or shock.

The most frequent adverse events include drowsiness, dizziness, constipation and nausea.

Please consult the full prescribing information we will be sending you for more information about the benefits and risks associated with KADIAN® that includes sections containing information about "Drug Abuse and Dependence," Overdosage" and "Dosage and Administration." The Dosage and Administration section also contains information about how to convert from other morphine products and other opioid products to KADIAN®.

CLOSE
Based on our conversation Dr, can I count on you to prescribe KADIAN® Capsules for appropriate patients?(Record Answer)
Dr, would you be interested in receiving co-pay cards for KADIAN® Capsules? (Record Answer)
Dr, you will need to write the full name, <b>KADIAN® Capsules</b> on the prescription and write "DAW" to ensure your patients receive the product you intended.
Dr, on behalf of Actavis and me, thank you for your time. If you have any further questions please feel free to contact us at 1-XXX-XXX-XXXX.

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## TMS Health Telesales Script Rev 5/12/118/31/11

# Call Introduction for KADIAN® (morphine sulfate extended release) Capsules CII:

IMPORTANT NOTE: If at any time during this call a medical concern is raised, please remind the physician to contact Actavis Medical Affairs at 1-888-496-3082.

Gatekeeper Opening
Good morning/afternoon. This is I am calling on behalf of Actavis. May I ask to whom I am speaking? (Record the name of the Gatekeeper). I would like to speak with Dr regarding an important update on the reimbursement status of KADIAN® (morphine sulfate extended release) Capsules in the state of the price of long acting opioids. ((insert state of doctor)) (May I speak with him/her?)
(If "YES" proceed to the PHYSICIAN SCRIPT/OPENING)
(If doctor is unavailable, follow steps below inserting where appropriate the gatekeeper and doctor's name)
1. May I hold for the possibility of reaching the doctor between patients? I will respect his/her time and be brief. I don't mind holding if that is okay with you. (If "Yes," proceed to PHYSICIAN SCRIPT/OPENING)
If it is not possible to hold
2. I really appreciate your help. I believe Dr will be interested in hearing about the cost of long acting opioids for your patientsformulary status for KADIAN® in your state I would like to make an appointment to speak to him/her at a time that is convenient – perhaps early morning/around noon hour or later in the evening?  **Thank you for your help. I look forward to speaking with Dr at that time.
If response is "There is no good time to speak to the doctor" or "He/she won't speak to you"
3. I understand it is difficult to reach him/her while seeing patients. May I leave my name and number and a message so he/she may contact me at his/her Revision Date: August 31May 12, 2011 1 KADI11622

convenience?

#### If response is "He/she won't call you either"

<ol><li>Is there a nurse pr</li></ol>				
able to speak with?	erncillance	am: procee	ed to PHI's	

If response is "No, he/she won't speak to you either" or "There is no NP or PA in this office" 5. Perhaps the nurse or Medical Assistant that works most closely with ? (Record Nurse's name and proceed to NURSE SCRIPT/OPENING, make an appointment or leave toll-free number if necessary) If at any point in the conversation you are asked to "fax or mail the information" 6. We would be glad to mail the doctor some information regarding the cost of long acting opioids to patients.a list of the formulary status for KADIAN®. May I confirm the doctor's mailing address? (Verify full name, business name, mailing address.) Thank you. When can I follow up on the information with Dr. \_\_\_\_\_ ? (If requested to send info to the NP/PA, Nurse or MA they should get their name for follow up as well). NURSE SCRIPT/OPENING Good morning/afternoon. My name is \_\_\_\_\_. I am calling on behalf of Actavis. Is this \_\_\_\_\_, the nurse for Dr. \_\_\_\_? (Ask and record name if not already secured) Thank you for taking my call; I will be brief. I am trying to reach Dr. regarding the cost of long acting opioids to patients.KADIAN® (morphine sulfate extended release) Capsules. In the state of ((insert state)), KADIAN® has excellent coverage for your patients on the following plans: ((Go to state-specific coverage)). In addition, your Medicare patients also have excellent access to KADIAN® on the following plans: ((Go to state-specific coverage)). When a generic morphine sulfate is prescribed, I presume that cost to your patients is a major factor in that decision. I'm calling today to explain why for a majority of your managed care patients, KADIAN can be a less expensive option than a generic product.

In 2010, the average cost to patients of all generic prescription products was \$6.06. 87% of KADIAN patients with managed care coverage pay less than \$50 for their prescription. If they use the KADIAN co-pay assistance card, which is

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good for the first \$50 of the patient's co-pay, they would actually pay \$0 for their KADIAN prescription.

I would be happy to send you more information about the KADIAN co-pay card and how the majority of your managed care patients can pay \$0 for their prescription.

NOTE: If asked, the co-pay card is not valid for prescriptions purchased under Medicaid, Medicare, federal or state drug programs, private indemnity or HMO insurance plans which reimburse patients for the entire cost of prescription drugs. The card is not valid in Massachusetts, except for cash paying patients.

Should your physician prescribe KADIAN®, I would like to make sure that the doctor is aware of this <u>informationformulary coverage.</u> Would it be possible to speak to Dr. at this time?

If doctor is unavailable, follow same steps as with Gatekeeper).

### PHYSICIAN SCRIPT/OPENING

Good morning/afternoon Dr	Thank you for taking my call, I will be
brief. My name is	I am calling on behalf of Actavis regarding
KADIAN® (morphine sulfate	extended release) Capsules.
((For physicians on the Embed	a® target list only)): Doctor, the last time we
spoke we discussed the Embed	da® recall. Have you transitioned your Embeda®
patients over to KADIAN® or to	a different product?"
((If transitioned at least some p	vatients to KADIAN®)): Thank you for the patients
you switched to KADIAN®. He	w do you make the decision on which product to
switch to? ((Note top reasons))	<del>.</del>

Note: Please do not probe or comment on the reasons given.

Today I'd like to speak to you about the <u>price of long acting opioids.formulary status on KADIAN®</u>. In the state of ((insert state)), KADIAN® has excellent coverage for your patients on the following commercial plans: ((Go to state-specific coverage)). In addition, your Medicare patients also have excellent access to KADIAN® on the following plans: ((Go to state-specific coverage)). When a generic morphine sulfate is prescribed, I presume that cost to your patients is a major factor in that decision. I'm calling today to explain why for a majority of your managed care patients, KADIAN can be a less expensive option than a generic product.

In 2010, the average cost to patients of all generic prescription products was \$6.06. 87% of KADIAN patients with managed care coverage pay less than \$50

Revision Date: August 31May 12, 2011 3 KADI11622 for their prescription. If they use the KADIAN co-pay assistance card, which is good for the first \$50 of the patient's co-pay, they would actually pay \$0 for their KADIAN prescription.

I would be happy to send you more information about the KADIAN co-pay card and how the majority of your managed care patients can pay \$0 for their prescription. Would you like me to mail a copy of the formulary status for KADIAN®this information to your office? (If "Yes" please take contact name and fax number and continue with script. If "No", continue with script).

NOTE: If asked, the co-pay card is not valid for prescriptions purchased under Medicaid, Medicare, federal or state drug programs, private indemnity or HMO insurance plans which reimburse patients for the entire cost of prescription drugs. The card is not valid in Massachusetts, except for cash paying patients.

Note: If you are cut-off at any time during the discussion of KADIAN's full indication, remind the HCP that KADIAN® is only appropriate for use in a very limited patient population who experience persistent moderate to severe pain. Also inform the HCP that following the call, you will be sending a copy of the KADIAN® PI which contains the full indication and risk information for their reference.

Note: If you are asked at any time for the status of KADIAN® on plans not on your list, please let the doctor/office staff know that you can find out and get back to them later. You may remind the doctor/office staff that KADIAN® has excellent managed care coverage with most plans at second or third tier; in fact, KADIAN® has formulary coverage for the majority of patients in the top 25 U.S. health plans. If you are asked for the status of another product aside from KADIAN®, please let them know that you do not have access to that information.

As you know, KADIAN® is 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® is also indicated for post-operative use only if the patient was already receiving KADIAN® prior to surgery or if the post-operative pain is expected to be moderate to severe and persist for an extended period of time.

KADIAN® is NOT indicated for pain in the immediate post-operative period (the first 12-24 hours following surgery), of or if the pain is mild or not expected to persist for an extended period of time.

KADIAN® is NOT intended for use as a PRN analgesic.

KADIAN® capsules are to be swallowed whole or the contents sprinkled on applesauce. The pellets in the capsules must not be chewed, crushed, or

Revision Date: <u>August 31May 12</u>, 2011 4 KADI11622 dissolved due the risk of rapid release and absorption of a potentially fatal dose of morphine.

You also might be interested to know that that Actavis offers a **KADIAN®** CO-PAY ASSISTANCE CARD PROGRAM for your patients. The card provides your patients with up to \$50.00 towards their KADIAN® prescription co-pay or out-of-pocket costs.

How do you decide which medication to prescribe for your patients with chronic pain?

Note: An HCP's response to the above question may give you an opportunity to provide additional information about KADIAN® capsules. When providing additional information or responding to questions, only communicate the most relevant/most appropriate statements from the list below that are responsive to the HCP's question. Do not read the entire list of statements unless all of the information is relevant to the discussion.

### ABOUT KADIAN®

Doctor, as you may recall

- KADIAN® contains morphine as its active ingredient and has a long history of safety and efficacy when used as indicated
- KADIAN® has a well known side effect profile
- KADIAN® provides steady blood levels of morphine sulfate with few peaks and valleys
- KADIAN® is stocked in pharmacies nationwide
- KADIAN® has excellent managed care coverage with most plans at second or third tier; in fact, KADIAN® has formulary coverage for the majority of patients in the top 25 U.S. health plans (source: AIS Directory of Health Plans: 2011, Fingertip Formulary (T2 and T3) and Data on File at Actavis Elizabeth LLC).
- KADIAN® is in a preferred position on many state public aid programs
- KADIAN® has a generous co-pay assistance program. Its' \$50 co-pay card significantly reduces the patient's out-of-pocket expenses
- KADIAN® Co-pay cards can be used 2x per month.

Revision Date: <u>August 31May 12</u>, 2011 5 KADI11622 KADIAN® Co-pay cards have no expiration date.

### KADIAN® DOSING

- KADIAN® is available in 8 different strengths and can be titrated in 10mg increments. The availability of these 8 doses provides flexibility in dose selection.
- KADIAN® provides convenience and flexibility with once or twice a day dosing.
- KADIAN® doses can be titrated up every other day.
- KADIAN does not have a ceiling or recommended maximal dose, especially in patients with chronic pain of malignancy. In such cases the total dose of KADIAN should be advanced until the desired therapeutic endpoint is reached or clinically-significant opioid-related adverse reactions intervene.
- KADIAN® has no significant food effect and can be administered without regard to meals for dosing convenience.
- KADIAN® is available as an extended release capsule, but it has 3 modes of administration.
  - the capsules can be swallowed whole:
  - o the contents of the capsule can be sprinkled on a small amount of applesauce at room temperature or cooler; or
  - The pellet contents of the capsule may be administered through a G-tube.
- The capsules are to be swallowed whole or the contents sprinkled on applesauce. The pellets in the capsules must not be chewed, crushed, or dissolved due the risk of rapid release and absorption of a potentially fatal dose of morphine.

Actavis will continue to assist your patients with (1) our Co-pay Assistance Program and (2) our Patient Assistance Program for those patients that cannot afford KADIAN® and qualify.

Do you currently have any KADIAN® Co-Pay Assistance Cards?

How often do you provide your patients with Co-Pay Assistance Cards?

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If the HCP uses co-pay cards/ would you like to receive additional co-pay assistance cards?

#### **FAIR BALANCE**

Note: If you are unable to complete the discussion of the fair balance information, inform the HCP that a copy of the PI will be sent for the HCP's information and proceed to CLOSE.

As you know, there also are risks associated with the use of KADIAN®.

KADIAN® contains morphine sulfate which is 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®.

KADIAN® 100mg and 200mg 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® is contraindicated in patients with a known sensitivity to morphine or any of its other ingredients, or in any situation where opioids are contraindicated including patients with respiratory depression acute or severe bronchial asthma or hypercarbia. KADIAN® should not be given to patients with gastrointestinal obstruction, particularly those with or suspected of having paralytic ileus.

KADIAN® may be expected to have additive effects when used with alcohol, other opioids, or drugs that cause central nervous system depression including sedatives, hypnotics, anesthetics, phenothiazines, and other tranquilizers.

Respiratory depression is the chief hazard of all morphine preparations and can occur more frequently in elderly or debilitated patients or in patients who also have other respiratory conditions. The effects may be more exaggerated in patients with head injuries or intracranial lesions.

KADIAN® may cause severe hypotension, orthostatic hypotension, and syncope and should be used with caution in patients with circulatory shock

KADIAN® should be discontinued 24 hours before a scheduled cordotomy or other interruption of pain transmission pathways.

KADIAN® should be used with caution in patients with biliary tract disease, including acute pancreatitis.

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KADIAN® may impair the mental and/or physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery.

KADIAN® should only be used in pregnancy if the need for strong opioid analgesia justifies the potential risk to the fetus. KADIAN® is not recommend for use in women during and immediately prior to labor. KADIAN® should not be used in nursing mothers.

KADIAN® has not been studied in patients below the age of 18 years. The range of doses available is not suitable for very young pediatric patients and the apple sauce sprinkling method of dosing is not an appropriate alternative for these patients.

KADIAN® should be dosed cautiously in elderly patients, usually starting at the low end of the dosing range.

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

The most frequent adverse events include drowsiness, dizziness, constipation and nausea.

Please consult the full prescribing information we will be sending you for more information about the benefits and risks associated with KADIAN® that includes sections containing information about "Drug Abuse and Dependence," Overdosage" and "Dosage and Administration." The Dosage and Administration section also contains information about how to convert from other morphine products and other opioid products to KADIAN®.

# CLOSE Based on our conversation Dr.

Based on our conversation Dr. \_\_\_\_\_\_, can I count on you to prescribe KADIAN® Capsules for appropriate patients?(Record Answer)

Dr. \_\_\_\_\_, would you be interested in receiving co-pay cards for KADIAN® Capsules?
(Record Answer)

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Dr	, you will need to write the full name, <b>KADIAN® Capsules</b> on the
prescription a intended.	and write "DAW" to ensure your patients receive the product you
Dr	, on behalf of Actavis and me, thank you for your time. If you
have any fur	ther questions please feel free to contact us at 1-XXX-XXX-XXXX.

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