

ZYPREXA “FREQUENT AREAS OF CONCERN” OR “FAOC”

1. *I do not treat that type of patient.*

Cushion: *Thanks for sharing that with me.*

Probe 1: *What concerns do you have in treating a patient like this? (or Donna) (This is a great place to “understand needs.” Is the PCP afraid of treating the disease state or afraid of the medications he/she will use?)*

Probe 2: *If you had safe and effective treatment options, how would that impact your decision on whether you treat a patient like Donna or refer them to a psychiatrist?*

Important notes: *a. Make sure the PCP recognizes the type of patient we are talking about today, not the psychotic patient or severely ill patient, but the complicated mood patient who has symptoms of irritability, anxiety, poor sleep and mood swings. This is most likely a patient he has seen for a few years and has felt comfortable treating. b. Having confirmed the patient type – it is now time to further understand the needs of the physician – and to satisfy those needs with Zyprexa.*

2. *Zyprexa is an anti-psychotic.*

Cushion: *That is correct, doctor. When Zyprexa was launched, our initial indication was for schizophrenia.*

Clarify: *What is it about anti-psychotics that you are concerned about?*

Address AOC: *The FDA has now classified Zyprexa as a psychotropic (see first line in PI), as it is the only medication indicated to treat **both** schizophrenia and bipolar mania. Zyprexa is indicated for both the short term and long term treatment of schizophrenia and acute bipolar mania. **Address AOC:** *Zyprexa’s safety profile is much more favorable than the older typical anti-psychotic agents you may be familiar with. Go to Favorable Safety Page (pg. 6 in Detail Aid) and address the concern.**

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Note: *The American Psychiatric Association recently updated its Standards of Care for Bipolar Illness and listed Zyprexa as first-line therapy.*

3. *I am concerned about EPS/TD.*

Cushion: *I understand your concern regarding EPS/TD*

Clarify: *Can you clarify your concern regarding EPS?*

Address AOC: (go to Favorable Safety page) EPS: *Zyprexa has a low risk of EPS, and in a study using the most exacting measurements, the Simpson Angus Scale, Zyprexa’s rate of EPS was comparable to placebo across all dose ranges (page 6) (if physician is utilizing/comparing with Risperdal). In a head-to-head study vs. Risperdal, the rate of EPS for Zyprexa was 12.5% vs. 22.3% for Risperdal. **TD:** *Zyprexa has a minimal risk for Tardive Dsykinesia (TD). In a**

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clinical trial vs. Haldol, the incidence of TD was .52% with Zyprexa vs. 7.45% with Haldol over a 1-year period.

Check for Agreement *How do you feel about this safety data?*

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4. *I am worried about sedation.*

Cushion: *Thanks for sharing with me.*

Clarify: *For a patient like Donna, who presents with irritability, anxiety, mood swings and disrupted sleep, how do you think somnolence may affect this patient?*

Address AOC: *The #1 side effect that occurred in clinical trials with Zyprexa was somnolence. It appears to be transient and may benefit some patients.*

Therefore, it is recommended to take Zyprexa either at bedtime or earlier in the evening. Now, if a patient is drowsy in the morning, remember that Zyprexa has a 6 hour Tpeak (time to peak concentration), so simply instructing your patient to take their tablet earlier in the evening, perhaps at dinner, may alleviate the morning drowsiness.

Check for Agreement *How do you feel about this safety data?*

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5. *I am concerned about weight gain.*

Cushion: *Thanks for letting me know your concern.*

Clarify: *Is this something you have seen in your patients or heard about?*

Address AOC: *Zyprexa may cause an increase in appetite that can lead to weight gain. The increase in appetite can be manageable, and diet and behavioral modifications can help. Many describe this as carb-craving so discussing this up front with your patients is helpful. You can suggest that patients drink diet soda instead of regular soda, or cut back on the amount of carbohydrates they eat. Some patients adopt a "1-plate rule" when they sit down for dinner. Increasing daily activity may also help manage weight*

Check for Agreement *How do you manage weight gain that results from other medications? If the physician has further questions, offer to have a medical letter sent to them.*

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6. *I am concerned about diabetes.*

Cushion: *Thank you for sharing this concern with me.*

Clarify: *Is this something you have seen or heard about?*

a. Address AOC: *I understand your concern. The incidence of diabetes is 2-4X more common in mentally ill patients than in the general population. In every study examining this subject, no causal relationship has been established between patients being treated with Zyprexa and the onset of diabetes. The incidence of diagnosed treatment-emergent diabetes with patients taking Zyprexa was comparable to those patients treated with Risperdal, Haldol and Depakote in every clinical study conducted by Lilly or by our competitors. These facts suggest that you should choose a medication based on its efficacy*

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in treating complicated mood symptoms, but to be aware of the incidence of diabetes in this population and address it appropriately.

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Important notes: *Confidence and correct tone is very important. We cannot dismiss this objection as a non-issue but rather we need to understand their concerns and address them appropriately.*

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