

# test questions PharmaCE™

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## ESZOPICLONE FOR INSOMNIA

### Goal

To discuss eszopiclone's pharmacology, mechanism of action, and pharmacokinetics; review evidence for efficacy and safety in transient and chronic insomnia in adults and geriatric patients; provide information on adverse events, drug interactions, dosing, and administration; and discuss patient counseling and formulary issues.

### Objectives

After reviewing this article, the reader should be able to:

1. describe the pharmacology, mechanism of action, and pharmacokinetics of eszopiclone, a non-benzodiazepine hypnotic agent;
2. interpret results of the key studies of eszopiclone for transient and chronic insomnia;
3. detect adverse effects of and drug interactions involving eszopiclone;
4. develop dosing recommendations for adults and geriatric patients;
5. provide patient counseling for eszopiclone.

### Test Questions

1. Although the exact mechanism of action of eszopiclone is not known, it is thought to interact with which of the following neurotransmitter systems?  
(a) norepinephrine  
(b) monoamine oxidase

- (c) serotonin  
(d) cholecystokinin  
(e) GABA

### 2. Which of the following statements describes the relationship between eszopiclone and zopiclone regarding its sedative effects?

- (a) Eszopiclone is the active S(+) isomer of zopiclone.
- (b) Zopiclone is a nonracemic compound.
- (c) The sedative effects of zopiclone are greater than those of eszopiclone.
- (d) Eszopiclone is the active R(-) isomer of zopiclone.
- (e) Zopiclone produces more relief of anxiety than eszopiclone.

### 3. Based on eszopiclone's metabolic elimination routes, drug interactions would be expected to occur with drugs that inhibit which of the following cytochrome P450 enzymes?

- (a) 1A2  
(b) 2C9  
(c) 2D6  
(d) 3A4  
(e) 2E1

### 4. How long is the elimination half-life of eszopiclone?

- (a) 1 hour  
(b) 6 hours  
(c) 12 hours  
(d) 18 hours  
(e) 24 hours

### 5. A major limitation of the Rosenberg et al. trial of eszopiclone in transient insomnia is which of the following?

- (a) The study lacked an active comparator agent.

- (b) Efficacy was evaluated using polysomnography.
- (c) The study population did not have insomnia.
- (d) Doses of eszopiclone used in the trial were too high.
- (e) The study duration was too short for evaluation.

### 6. In the 6-week study of patients with chronic insomnia conducted by Zammit et al., eszopiclone 3 mg, but not 2 mg, produced a significant reduction in which of the following parameters compared with placebo?

- (a) DSST  
(b) sleep onset  
(c) sleep efficiency  
(d) total sleep time  
(e) sleep maintenance

### 7. Results of the Roth et al. study are important for which of the following reasons?

- (a) Information on management of transient insomnia is presented.
- (b) Only women were included in the trial.
- (c) This was a flexible-dose trial of eszopiclone.
- (d) Data for 12 months of eszopiclone usage are provided.
- (e) Polysomnography was used as an objective measure.

### 8. A 74-year-old woman with angina and diabetes presents a prescription for 15 tablets of eszopiclone 1 mg. The directions are to take one tablet at bedtime. She tells you that she has experienced difficulties staying asleep since her husband was placed in a nursing home 6 weeks ago. She is taking metformin, aspirin, and isosorbide dinitrate. Based on the results of the Scharf et al. trial, what recommendation would you make to her physician?

- (a) Increase the dose to 2 mg to help with sleep maintenance.
- (b) Decrease the dose to 0.5 mg because it is too high.
- (c) Increase the dose to 3 mg to ensure both sleep onset and maintenance.
- (d) Take the medication every other night to prevent withdrawal effects.
- (e) Switch to temazepam 7.5 mg at bedtime because it is cheaper.

### 9. A nurse practitioner consults with you regarding a 56-year-old man who has taken eszopiclone 3 mg for 12 nights. The patient complains that he is still unable to fall asleep and thinks his insomnia has actually worsened. What recommendation do you make to the nurse practitioner?

- (a) Increase the dose to 4 mg for better efficacy in maintaining sleep.
- (b) Evaluate the patient for a primary psychiatric or medical illness.
- (c) Switch to flurazepam 15 mg at bedtime because it has a longer  $t_{1/2}$ .
- (d) Change the administration time to 2 hours before bedtime.
- (e) Add trazodone 100 mg to augment eszopiclone's effects.

10. A 23-year-old male graduate student had a prescription for eszopiclone filled a week ago and presents today inquiring about the common adverse effects of this new prescription. You reply that the most common adverse effects with eszopiclone are which of the following?

- (a) metallic taste, sweating, dizziness
- (b) bitter taste, rash, dizziness
- (c) stomatitis, hives, sedation
- (d) dry mouth, pruritus, nausea
- (e) hypersalivation, sweating, fatigue

11. A 46-year-old female attorney has been taking eszopiclone for 3 months and presents to the hospital for depressed mood with suicidal ideation following stressors with personal finances and a breakup of a relationship with her fiancé. She has a history of depression and was treated successfully with sertraline 5 years ago. Which of the following antidepressants should be avoided in this patient?

- (a) nefazodone
- (b) bupropion
- (c) venlafaxine
- (d) mirtazepine
- (e) escitalopram

12. Which of the following statements distinguishes eszopiclone from zaleplon and zolpidem?

- (a) Eszopiclone is effective for chronic insomnia.
- (b) Eszopiclone has a shorter  $t_{1/2}$ .
- (c) Eszopiclone has fewer drug interactions.
- (d) Eszopiclone is less expensive.
- (e) Eszopiclone is more effective in transient insomnia.

13. A 40-year-old woman presents with a new prescription for 15 tablets of eszopiclone 2 mg qhs. Patient counseling should include which of the following statements?

- (a) Take eszopiclone 2 hours before bedtime for best results.
- (b) For eszopiclone to work best, take it with a high-fat, heavy meal.
- (c) Do not use alcohol while taking eszopiclone.
- (d) If the 2-mg dose is not effective, she may increase it to 3 mg qhs.
- (e) Eszopiclone has been found to be safe in pregnancy.

14. A 50-year-old man with chronic renal failure, diabetes, and hypertension has chronic insomnia. How should the dosage of eszopiclone be adjusted for this patient?

- (a) The starting dose should be reduced by one-half.
- (b) The starting dose should be reduced by one-third.
- (c) The starting dose does not require adjustment.
- (d) The starting dose should be increased to 4 mg at bedtime.
- (e) The dose should be taken one hour before bedtime.

15. Which of the following clinical situations requires an alteration in the starting dose of eszopiclone?

- (a) renal impairment and pregnancy
- (b) hepatic impairment and ketaconazole
- (c) female and lithium
- (d) atrial fibrillation and warfarin
- (e) epilepsy and phenytoin

- (b) pantoprazole
- (c) esomeprazole
- (d) omeprazole
- (e) lansoprazole

5. Which of the following PPI liquid formulations has been shown to have the lowest relative bioavailability (vs the intact tablet or capsule)?

- (a) immediate-release omeprazole for suspension mixed in water
- (b) lansoprazole mixed in 8.4% sodium bicarbonate
- (c) lansoprazole oral disintegrating tablet mixed in water
- (d) esomeprazole mixed in water
- (e) omeprazole mixed in 8.4% sodium bicarbonate

6. In which of the following patient scenarios would genetic polymorphism most likely occur?

- (a) a white male prescribed rabeprazole
- (b) an Asian male prescribed rabeprazole
- (c) an Asian male prescribed omeprazole
- (d) a white male prescribed omeprazole
- (e) a white female prescribed rabeprazole

7. Optimal intravenous therapy for a patient with a recent peptic ulcer bleed who has undergone endoscopy would be:

- (a) esomeprazole 20 mg daily to achieve a gastric pH >4.
- (b) lansoprazole 90-mg bolus, then 6 mg/h to achieve a gastric pH >6.
- (c) lansoprazole 30 mg every 12 hours to achieve gastric pH >6.
- (d) pantoprazole 40 mg daily to achieve a gastric pH >6.
- (e) pantoprazole 40 mg every 8 hours to achieve a gastric pH >4.

8. A newly developed PPI is found in a study in healthy volunteers to raise the gastric pH to >4 for 11 hours after administration of the first dose. What is the greatest limitation of this study?

- (a) The relative magnitude of acidity below the threshold is not captured.
- (b) In any high pH environment, a change in gastric pH will be exaggerated.
- (c) The finding avoids the need to complete comparative studies with clinical outcomes.
- (d) In any low pH environment, a change in pH will be masked.
- (e) This study chose to use a pH threshold rather than a median pH.

9. The feeding tube of a patient who recently received a PPI liquid formulation is found to be plugged. Which of the following formulations was most likely to have been administered?

- (a) the contents of an esomeprazole capsule mixed in water
- (b) a lansoprazole oral disintegrating tablet mixed in water
- (c) the contents of a lansoprazole capsule mixed in water

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### PPI CONSIDERATIONS: PART 1

#### Goal

To review important PPI pharmacologic, pharmacokinetic, and pharmacodynamic principles in acutely ill patients, compare PPI formulation options for patients unable to swallow a tablet or capsule, and provide clinicians with guidance when making hospital formulary decisions with this class of agents.

#### Objectives

After reviewing this article, the reader should be able to:

1. describe the pharmacology and pharmacokinetics of available PPIs;
2. discuss the pharmacodynamic parameters used to evaluate response to PPI therapy and differences between available PPIs;
3. differentiate between currently available PPI suspension and injectable formulations.

#### Test Questions

1. Which of the following are mechanisms of action for PPIs?

- (a) enters the parietal cell through the basolateral membrane
- (b) becomes activated in the acidic canalicular space
- (c) covalently binds to cysteine residues on the proton pump
- (d) All of the above are correct.
- (e) None of the above is correct.

2. Which of the following accounts for the 3- to 4-day lag time to reach maximum acid-suppressive effect after PPI therapy is initiated?

- (a) rebound acid hypersecretion
- (b) upregulation of receptors
- (c) rebound acid hypersecretion
- (d) irreversible binding to proton pumps
- (e) None of the above is correct.

3. Which of the following phenomena associated with  $H_2$ -receptor antagonists is *not* associated with PPIs?

- (a) drug interactions due to an increase in the intragastric pH
- (b) tolerance
- (c) autoinhibition
- (d) genetic polymorphism in metabolism
- (e) low oral bioavailability

4. Which of the following PPIs is available as an orally disintegrating tablet that can be placed on the tongue or dissolved in water for administration through a feeding tube?

- (a) rabeprazole

- (d) the contents of a lansoprazole capsule mixed in sodium bicarbonate
- (e) immediate-release omeprazole suspensions mixed in water

**10. Which of the following intravenous PPI regimens is ordered *least* correctly?**

- (a) esomeprazole 40-mg bolus over 3 minutes
- (b) esomeprazole 40-mg infusion over 10 minutes
- (c) pantoprazole 40-mg bolus over 2 minutes
- (d) lansoprazole 30-mg bolus over 3 minutes
- (e) lansoprazole 30-mg infusion over 30 minutes

**11. Which of the following minibags should be discarded?**

- (a) esomeprazole in D5W minibag made 7 hours ago
- (b) esomeprazole in saline minibag made 7 hours ago
- (c) lansoprazole in D5W minibag made 10 hours ago
- (d) lansoprazole in saline minibag made 22 hours ago
- (e) pantoprazole in saline minibag made 16 hours ago

**12. Which of the following PPI formulations would be *most* optimal for a patient with a recent stroke who has difficulty swallowing a tablet or capsule?**

- (a) intravenous pantoprazole
- (b) lansoprazole mixed in 8.4% sodium bicarbonate
- (c) omeprazole mixed in 8.4% sodium bicarbonate
- (d) the contents of a lansoprazole capsule mixed in applesauce
- (e) lansoprazole oral disintegrating tablet

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**5-AZACYTIDINE AND DECITABINE**

**Goal**

To evaluate the structure–activity relationships, pharmacokinetics, pharmacology, toxicology, and results of available clinical trials of 5-AzaC and decitabine in the treatment of myelodysplastic disorders.

**Objectives**

After reviewing this article, the reader should be able to:

1. compare and contrast the chemical structure and structure–activity relationships of 5-AzaC and decitabine and the proposed mechanisms of action of DNA hypomethylating agents in general;
2. characterize the pharmacologic and toxicologic effects of the DNA hypomethylating agents, including the differences between 5-AzaC and decitabine;
3. discuss the results of clinical trials involving 5-AzaC and decitabine

therapy of MDS and transformed myeloid leukemia;

4. list the possible adverse effects of 5-AzaC and decitabine and identify patients at high risk for adverse effects;
5. recommend appropriate dosing and administration of 5-AzaC or decitabine to patients undergoing therapy for MDS.

**Test Questions**

**1. What is 5-AzaC and decitabine’s purported mechanism of action that leads to activation of previously silenced genes in neoplastic tissues?**

- (a) hypomethylation of DNA
- (b) hypermethylation of DNA
- (c) hypomethylation of RNA
- (d) hypermethylation of RNA
- (e) DNA intercalation

**2. What is a common early effect of hypomethylating agents regarding blood cell counts?**

- (a) thrombocytopenia
- (b) pancytopenia
- (c) leukocytopenia
- (d) leukocytosis
- (e) agranulocytosis

**3. Which of the following statements concerning 5-AzaC and decitabine is *false*?**

- (a) Decitabine preferentially reduces DNA methylation.
- (b) 5-AzaC preferentially reduces RNA and, to a lesser extent, DNA methylation.
- (c) Decitabine is a more potent reducer of DNA methylation.
- (d) Decitabine preferentially reduces RNA methylation.
- (e) DNA hypomethylation may affect transcription and differential gene expression.

**4. Reduced expression of which gene is thought to result in loss of cell cycle control and is related to disease progression in MDS?**

- (a) p15
- (b) p21
- (c) CDH1
- (d) BrCA1
- (e) APAK-1

**5. For cytidine analogs to be active as antineoplastic agents, they must undergo an activation by which of the following enzymes?**

- (a) ribonucleotide reductase
- (b) deoxycytidine kinase
- (c) thymidylate synthetase
- (d) DNA polymerase
- (e) adenosine deaminase

**6. Metabolic deactivation of cytidine derivatives occurs primarily by:**

- (a) deamination in leukemia cells.
- (b) base hydrolysis in hepatic cells.
- (c) sugar oxidation in hepatic cells.
- (d) phosphorylation in leukemia cells.
- (e) phosphorylation in hepatic cells.

**7. Which is the primary route of elimination of 5-AzaC?**

- (a) hepatic metabolism
- (b) renal elimination
- (c) excretion in the bile
- (d) both hepatic metabolism and biliary excretion
- (e) Route of elimination is not known.

**8. At therapeutic doses of decitabine, a white blood cell nadir was observed at what day after initial dosing?**

- (a) 8
- (b) 15
- (c) 22
- (d) 25
- (e) 28

**9. Clinical studies have shown that decitabine administration is most effective when:**

- (a) given as a bolus dose with bridge therapy to reach a steady-state concentration.
- (b) reaching a clinically significant cumulative dose.
- (c) given in shorter consecutive doses over a clinically significant period.
- (d) given as a predetermined cumulative dose over longer or continuous infusions.
- (e) given as an intramuscular depot injection.

**10. MDS arises from an abnormal:**

- (a) multipotent progenitor cell.
- (b) erythroid progenitor cell.
- (c) thrombocyte progenitor cell.
- (d) lymphoid progenitor cell.
- (e) reticulocyte cell.

**11. All of the following are subgroups of MDS according to the FAB system *except*:**

- (a) RA.
- (b) RARS.
- (c) RAEB.
- (d) CMML.
- (e) refractory pancytopenia.

**12. Compared with supportive treatment, 5-AzaC therapy of MDS has been shown in randomized clinical trials to cause which of the following responses?**

- (a) increased time to leukemic transformation or death
- (b) significantly improved quality of life, particularly by decreasing fatigue and dyspnea
- (c) significantly reduced the risk of leukemic transformation
- (d) significantly reduced the need for blood transfusions
- (e) All of the above responses were observed.

**13. Which factor was found to be highly predictive of survival rate in patients with MDS treated with decitabine?**

- (a) IPSS subgroup classification
- (b) FAB group classification
- (c) increased platelet count after one cycle of therapy
- (d) renal function
- (e) baseline albumin <30 g/L

**14. The most common adverse effects of 5-AzaC and decitabine are nausea, vomiting, and leukopenia. Without reducing therapeutic effectiveness, these adverse effects were reduced by which of the following methods of administration?**

- (a) lower doses and repetitive intravenous bolus dosing
- (b) continuous infusion dosing
- (c) central venous catheter
- (d) intramuscular depot dosing
- (e) reduction of dose only

**15. Which of the following statements regarding the mutagenic, carcinogenic, and teratogenic profiles of 5-AzaC and decitabine is true?**

- (a) Both drugs are mutagenic, carcinogenic, and teratogenic.
- (b) Only 5-AzaC is mutagenic, carcinogenic, and teratogenic.
- (c) Both drugs are teratogenic; 5-AzaC is also mutagenic and carcinogenic.
- (d) Both agents are mutagenic and carcinogenic; 5-AzaC is also teratogenic.
- (e) Only decitabine is mutagenic, carcinogenic, and teratogenic.

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## STATINS IN TYPE 2 DIABETES

### Goal

To provide an overview of 2 landmark clinical trials in lipid management, as well as a review of key concepts in both primary and secondary cardiovascular prevention as it relates to lipid management.

### Objectives

After reviewing this article, the reader should be able to:

- 1. identify the key points from recent trials in lipid management in patients with diabetes;
- 2. evaluate a patient's risk for cardiovascular events and list goals for LDL-C in a patient with diabetes for both primary and secondary cardiovascular prevention;
- 3. given a specific patient case or scenario, select an appropriate lipid drug regimen in a patient with diabetes.

### Test Questions

**1. The majority of the direct costs associated with treating type 2 diabetes go toward treating:**

- (a) CHD.
- (b) diabetic retinopathy.
- (c) hyperglycemia.
- (d) diabetic nephropathy.
- (e) diabetic foot ulcers.

**2. Which of the following statements is true regarding clinical trials in lipid management published prior to the last executive summary from the ATP in 2001?**

- (a) Fibrates (eg, gemfibrozil) were the most common intervention medication assessed.
- (b) They were focused almost exclusively on the primary prevention of cardiovascular disease.
- (c) They contained too few patients with diabetes to adequately assess lipid-lowering benefits in this population.
- (d) They were largely unsuccessful in delineating the benefits of lipid management in primary or secondary cardiovascular prevention.

- (e) They were focused almost exclusively on the secondary prevention of cardiovascular disease.

**3. The primary target of lipid management per the ATP is:**

- (a) TGs.
- (b) HDL-C.
- (c) LDL-C.
- (d) total cholesterol.
- (e) non-HDL-C.

**4. Which of the following statements regarding the HPS is true?**

- (a) Compared with other lipid studies, it contained the largest number of patients with diabetes.
- (b) It was solely a primary cardiovascular prevention study.
- (c) It was solely a secondary cardiovascular prevention study.
- (d) Other landmark lipid studies had larger total study populations.
- (e) It compared high-dose atorvastatin (80 mg daily) with lower-dose pravastatin (40 mg daily) therapy.

**5. Which of the following results of the HPS is true?**

- (a) First major coronary events were not significantly reduced.
- (b) Coronary mortality was not significantly reduced.
- (c) First non-fatal myocardial infarction events were not significantly reduced.
- (d) Incidence of stroke was not significantly reduced.
- (e) All-cause mortality was not significantly reduced.

**6. Which of the following statements regarding the CARDS is true?**

- (a) It was solely a secondary cardiovascular prevention study.
- (b) It was both a primary and secondary cardiovascular prevention study.
- (c) It compared high-dose atorvastatin (80 mg daily) with lower-dose pravastatin (40 mg daily).
- (d) It was the largest study to assess the benefits of statin therapy solely in patients with diabetes.
- (e) Only patients with high baseline levels (>160 mg/dL) of LDL-C benefited from statin therapy.

**7. Which of the following statements about the results of the CARDS is true?**

- (a) It failed to show a significant reduction in the composite outcome of acute CHD event, coronary revascularization procedure, or stroke.
- (b) It failed to show a significant reduction in all-cause mortality.
- (c) It failed to show a significant reduction in stroke.
- (d) It failed to show a significant reduction in acute coronary events.
- (e) It failed to show a significant reduction in acute cardiovascular events.

**8. With regard to primary cardiovascular prevention and lipid management, which of the following is true?**

- (a) Diabetes is considered a cardiovascular risk equivalent.

- (b) No further benefit of CHD event risk reduction is found with LDL-C concentrations <130 mg/dL.

- (c) There are conflicting goals for LDL-C between the ATP III and the ADA for patients with diabetes and no history of CVD.

- (d) The goal LDL-C, per the ATP III's last recommendations, of <70 mg/dL should be considered an option.

- (e) Regardless of baseline LDL-C levels, a 50–60% reduction in LDL-C is warranted.

**9. A 56-year-old male has a history of type 2 diabetes and hypertension. His past medical history is negative for CVD. His fasting lipid panel today shows total cholesterol 220 mg/dL, LDL-C 147 mg/dL, HDL-C 41 mg/dL, and TGs 159 mg/dL. What is the goal LDL-C?**

- (a) <70 mg/dL
- (b) <100 mg/dL
- (c) <130 mg/dL
- (d) <160 mg/dL
- (e) <190 mg/dL

**10. A 66-year-old female has had type 2 diabetes for 16 years. She has no other comorbidities, and her past medical history is negative for CVD. Her fasting lipid panel today shows total cholesterol 206 mg/dL, LDL-C 128 mg/dL, HDL-C 54 mg/dL, and TGs 121 mg/dL. Based on data from the HPS and CARDS, what percent reduction in LDL-C is warranted?**

- (a) 5–9%
- (b) 10–20%
- (c) 21–25%
- (d) 30–40%
- (e) 50–60%

**11. A 72-year-old male has a history of type 2 diabetes and peripheral vascular disease. He had an ischemic stroke 3 years ago. Based on the update from the ATP, what is the goal LDL-C?**

- (a) <70 mg/dL
- (b) <80 mg/dL
- (c) <130 mg/dL
- (d) <140 mg/dL
- (e) <160 mg/dL

**12. A 59-year-old female has a history of both hypertension and type 2 diabetes, but no history of CVD. Her fasting cholesterol panel today reveals an LDL-C of 121 mg/dL, which is similar to another level obtained 2 weeks ago. Her other lipid levels are total cholesterol 187 mg/dL, TGs 149 mg/dL, and HDL-C 52 mg/dL. Which of the following is the most appropriate action?**

- (a) No intervention is needed; her LDL-C is at goal.
- (b) Instruct her to improve her diet and exercise more. No lipid-lowering agent is necessary.
- (c) Instruct her to improve her diet, exercise more, and start gemfibrozil 600 mg twice daily.
- (d) Instruct her to improve her diet, exercise more, and start niacin 500 mg twice daily.
- (e) Instruct her to improve her diet, exercise more, and start atorvastatin 10 mg once daily.