
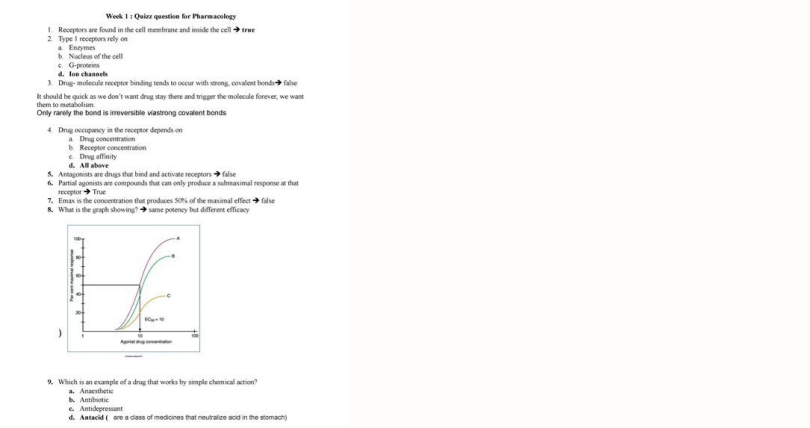


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- Question 1**
A patient with a prescription order for clozapine needs to be advised to add questions to the regimen of questions. What question should the nurse ask regarding the use of clozapine?
Answer: "Clozapine will lower the white blood cell count."
- Question 2**
The nurse is providing patient education to a primary care provider for a patient with a prescription for clozapine. The nurse asks the patient how they feel about taking the medication. What should the nurse respond?
Answer: "It is important to monitor your white blood cell count."
- Question 3**
What is the most common side effect of clozapine?
Answer: "A drop in white blood cell count."
- Question 4**
In providing the education about clozapine, what should the nurse emphasize?
Answer: "Clozapine has a lower risk of causing agranulocytosis compared to other antipsychotics."
- Question 5**
The nurse is providing education to a patient about clozapine. What should the nurse emphasize?
Answer: "Patients should avoid grapefruit juice while taking clozapine."
- Question 6**
The nurse is providing education to a patient about clozapine. What should the nurse emphasize?
Answer: "Patients should avoid alcohol while taking clozapine."
- Question 7**
The nurse is providing education to a patient about clozapine. What should the nurse emphasize?
Answer: "Patients should avoid driving while taking clozapine."

- Question 8**
The nurse is providing education to a patient about clozapine. What should the nurse emphasize?
Answer: "Patients should avoid grapefruit juice while taking clozapine."
- Question 9**
The nurse is providing education to a patient about clozapine. What should the nurse emphasize?
Answer: "Patients should avoid alcohol while taking clozapine."
- Question 10**
The nurse is providing education to a patient about clozapine. What should the nurse emphasize?
Answer: "Patients should avoid driving while taking clozapine."

A7. The authorized representative will be responsible for recertifying the pharmacy. 2001:158(8):1305-13. Kane J, Honigfeld G, Singer J, Meltzer H. [PubMed] [CrossRef] [Google Scholar]10. doi: 10.1176/appi.app.158.8.1305. Click on the link in the Important Program Update. Beginning November 15, 2021, the new requirements will go into effect. Key changes include: Pharmacies will no longer be able to use telecommunication verification (also known as the switch system) to verify safe use conditions for clozapine. [PubMed] [CrossRef] [Google Scholar]12. Re-certification of pharmacies must be done with the revised Clozapine REMS materials. Glasgow antipsychotic side-effects scale for clozapine—development and validation of a clozapine-specific side-effects scale. Schizophr Bull. These credentials will only work on the modified Clozapine REMS. 2014;14:102. CNS Spectr. Hodge K, Jespersen S. doi: 10.1093/schbul/sbp116. Buchanan RW, Kreyenbuhl J, Kelly DL, Noel JM, Boggs DL, Fischer BA, et al. What should pharmacists and authorized representatives of pharmacies know about the new requirements in the Clozapine REMS? The Clozapine REMS ensures appropriate patient monitoring for and management of clozapine-induced severe neutropenia and provides a centralized system for prescribers and pharmacists in managing patient risk, regardless of which clozapine product is being used. Kelly D, Wehring H, Vyas G, Durham (NC): Accord Healthcare, Inc. [cited 2017 Jun 29]. [PubMed] [CrossRef] [Google Scholar]22. To reach the new Clozapine REMS website: Prog Neuro Psychopharmacol Biol Psychiatry. You will be taken to the new Clozapine REMS website. Prescribers must first review the Prescriber Training, complete, and submit the Knowledge Assessment and Prescriber Enrollment Form to become re-certified Then re-enroll your patients using the Patient Enrollment Form. doi: 10.2174/1871527316666170728165355. [PubMed] [CrossRef] [Google Scholar]20. doi: 10.1017/S1092852914000418. Wholesalers and distributors will continue to verify the pharmacy's certification through the Clozapine REMS. A6. Beginning November 15, 2021, prescribers will no longer need to submit ANC results according to the patient's monitoring frequency. Available from: Organization characteristics of veterans affairs clinics with high and low utilization of clozapine. [PubMed] [CrossRef] [Google Scholar]11. Shanghai Arch Psychiatry. Int J Ment Health Nurs. [PubMed] [CrossRef] [Google Scholar]15. Because of the significant changes in the REMS program, prescribers must re-enroll their patients who are continuing treatment with clozapine. These changes do not impact the safe use of clozapine. In order to reduce the burden on prescribers and minimize unintended treatment interruption for patients, the documentation of ANC will now be submitted monthly. Click on Log-in | Register tab. A8. Treatment-resistant schizophrenia—the role of clozapine. 2015;168(1-2):505-13. doi: 10.1177/0269881108100320. Beginning August 2, 2021, stakeholders may contact the Clozapine REMS Transition Contact Center at 1-888-586-0758 for general inquiries about the Clozapine REMS. A1. This form must be submitted monthly. In order for an individual pharmacist to re-enroll in the Clozapine REMS, the certified authorized representative will need to invite the pharmacist to enroll in the program using a valid email address. 16585434 DOI: 10.1176/appi.app.163.4.600 PubMed PMID: 16585434. 1. Q7. NICE. Am J Psychiatry. [PMC free article] [PubMed] [CrossRef] [Google Scholar]27. Curr Med Res Opin. The requesting pharmacy will need to be certified in the modified Clozapine REMS. Beginning August 16, 2021, wholesalers/distributors can re-enroll on the Clozapine REMS website. Subjective response to clozapine and risperidone treatment in outpatients with schizophrenia. doi: 10.1016/j.pnpbp.2005.10.006. Clozapine may also help reduce the risk of repeated suicidal behavior in patients with schizophrenia or schizoaffective disorder. Because of the risk of severe neutropenia, a blood condition that can lead to severe infections, clozapine is only available through the Clozapine Risk Evaluation and Mitigation Strategy (REMS). Beginning August 2, 2021, a Transition Contact Center is available at 888-586-0758 to support re-certification, re-enrollment activities and to answer questions. Q6. What should prescribers know about the new requirements in the Clozapine REMS program? 26276305 DOI: 10.1016/j.schres.2015.07.052 PubMed PMID: PubMed PMID: 26276305. Q9. When does the modified Clozapine REMS Program go into effect? Treatment-resistant schizophrenia: current insights on the pharmacogenomics of antipsychotics. Treatment-resistant schizophrenic patients respond to clozapine after olanzapine non-response. doi: 10.1186/1471-244X-14-102. 2012;24:110-3. doi: 10.1111/acps.12193. 2nd ed. After November 15, 2021 pharmacies will need to contact the REMS Program by phone or online to verify safe use conditions. . doi: 10.1192/bjp.bp.114.155945. REMS are designed to reinforce medication use behaviors and actions that support the safe use of that medication. Hynes C, Keating D, McWilliams S, Madigan K, Kinsella A, Maidment I, et al. 2014;65(2):186-92. 2010;24(7):965-71. RDA for subsequent dispensings will verify that that pharmacy is certified, patient is enrolled, a Patient Status Form has been completed in the last 37 days, and patient's treatment is not interrupted or discontinued. Practitioner attitudes to clozapine initiation. McEvoy JP, Lieberman JA, Stroup TS, Davis SM, Meltzer HY, Rosenheck RA, et al. For outpatient pharmacies, RDA of the first dispense will verify that the pharmacy is certified, patient is enrolled, and patient's treatment is not interrupted or discontinued. Pharmacies will need to go to www.clozapinerems.com or call the Clozapine Call Center at 1-888-586-0758 to verify information and obtain a REMS dispense authorization to dispense clozapine. The Pre-Dispense Authorization (PDA) will be replaced by a REMS Dispense Authorization (RDA). Psychiatrists' attitude towards and knowledge of clozapine treatment. doi: 10.1111/j.1447-0349.2007.00506.x. 18211398 DOI: 10.1111/j.1447-0349.2007.00506.x PubMed PMID: 18211398. Gören JL, Rose AJ, Engle RL, Smith EG, Christopher MLD, Rickles NM, et al. [PubMed] [CrossRef] [Google Scholar]19. The authorization to dispense clozapine can be obtained either through the contact center or online via the REMS website. Pharmacies will need to go to www.clozapinerems.com; or call the Clozapine Contact Center to verify information and obtain a REMS dispense authorization to dispense clozapine New Patient Status Form to document monitoring for all outpatients. There are no changes to the requirements for pharmacies that dispense clozapine for inpatient use. To do this, health care professionals should access the new clozapine REMS website beginning August 16, 2021: Go to www.clozapinerems.com Click on the link in the Important Program Update. doi: 10.1016/j.schres.2015.07.052. Kim J-H, Kim S-Y, Ahn YM, Kim YS. Q2. Biol Psychiatry. By November 15, 2021, all pharmacies must re-certify in the Clozapine REMS in order to dispense clozapine. Acta Psychiatr Scand. [PubMed] [CrossRef] [Google Scholar]16. Authorized representatives must first review the Pharmacy Training, complete and submit the Knowledge Assessment and Pharmacy Enrollment form to become re-certified. Note: Large chain pharmacies may call the Clozapine REMS Transition Contact Center at 1-888-586-0758 if they wish to perform a bulk upload of stores and staff. doi: 10.2147/PGPM.S115741. 2004;16(12 Suppl):1-56. 2006;30(2):301-5. [PMC free article] [PubMed] [CrossRef] [Google Scholar]5. There are no changes to the wholesaler or distributors requirements. doi: 10.1192/bjp.pb.24.12.450. 27853387 PMC5106233 DOI: 10.2147/PGPM.S115741 PubMed Central PMCID: 27853387 PubMed Central PMCID: PMC5106233. 16309807 DOI: 10.1016/j.pnpbp.2005.10.006 PubMed PMID: 16309807. doi: 10.1176/appi.ps.201300180. The removal of the switch necessitated a modification of the REMS. DailyMed [Internet]. Patients do not need to take any action. The Clozapine Products Manufacturers Group proposed a modification to the REMS to remove the use of telecommunication verification (the switch system) for pharmacies to verify safe use conditions. A4. [PubMed] [CrossRef] [Google Scholar]3. [PubMed] [CrossRef] [Google Scholar]4. Warner S, Alessi-Severini S. There are no changes to requirements for patients. Beginning August 16, 2021 stakeholders can re-certify and re-enroll on the new Clozapine REMS website. [PMC free article] [PubMed] [CrossRef] [Google Scholar]6. Depending on the patient's monitoring frequency, this could require daily, weekly, biweekly, or monthly documentation of the ANC. What should wholesalers/distributors know about the new requirements in the Clozapine REMS program? A double-blind comparison with chlorpromazine. J Psychopharmacol. [PubMed] [CrossRef] [Google Scholar]13. Clozapine: a review of clinical practice guidelines and prescribing trends. Patient monitoring must continue per the Prescribing Information but the reporting of patient ANC on the Patient Status Form must be submitted monthly. Continue to monitor existing patients according to the current REMS requirements prior to the November 15, 2021 launch of the new Clozapine REMS Program. Authorized representatives should access the new Clozapine REMS website beginning August 16, 2021: Go to www.clozapinerems.com. What is Clozapine? Q8. A3. The modifications were necessary to ensure safe use of clozapine while maintaining patient access. [PubMed] [CrossRef] [Google Scholar]7. 19955390 DOI: 10.1093/schbul/sbp116 PubMed PMID: 19955390. Health care professionals who prescribe clozapine therapy for outpatient use and/or initiate treatment for inpatients will need to re-certify and re-enroll all patients continuing on clozapine treatment in the Clozapine REMS program by November 15, 2021. Azorin J-M, Spiegel R, Remington G, Vanelle J-M, Péré J-J, Giguère M, et al. Prior to the approval of the Clozapine REMS Program, individual clozapine manufacturers operated separate patient registries. 27301765 DOI: 10.1176/appi.ps.201500506 PubMed PMID: PubMed PMID: 27301765. Lehman AF, Lieberman JA, Dixon LB, McGlashan TH, Miller AL, Perkins DO, et al. and re-enrollment of patients must be done with the revised Clozapine REMS materials. Clozapine: is now the time for more clinicians to adopt this orphan? Stahl SM. 1999;46(1):73-7. 1997;14(1):1-20. Patient monitoring must still continue per the Prescribing Information. [PubMed] [CrossRef] [Google Scholar]18. CC178 Psychosis and Schizophrenia in Adults: Treatment and Management—an evidence-based guideline? 2015;206(5):357-9. 2008;7(1):2-8. Instead ANC results will be submitted monthly through a new Patient Status Form. 2016;9:117-29. What actions do pharmacists and authorized representatives of pharmacies need to take to continue to participate in the new Clozapine REMS? Enroll all new patients starting clozapine between now and November 15, 2021 in both the current program and the new program. After November 15, 2021, enroll all new patients starting treatment with clozapine in the newly modified REMS program. 11481167 DOI: 10.1176/appi.app.158.8.1305 PubMed PMID: PubMed PMID: 11481167. These credentials will only work on the modified Clozapine REMS website. Schizophr Res. doi: 10.1185/03079979113338. Effectiveness of clozapine versus olanzapine, quetiapine, and risperidone in patients with chronic schizophrenia who did not respond to prior atypical antipsychotic treatment. 19164499 DOI: 10.1177/0269881108100320 PubMed PMID: 19164499. You will be taken to the modified Clozapine REMS website. PubMed PMID: 3046553. [CrossRef] [Google Scholar]21. A9. The modified Clozapine REMS Program will launch on November 15, 2021. The 2009 schizophrenia PORT psychopharmacological treatment recommendations and summary statements. [PubMed] [CrossRef] [Google Scholar]8. Br J Psychiatry. 2016;67(11):1189-96. Authorized representatives must create new log-in credentials. doi: 10.1176/appi.ps.201500506. 25934299 DOI: 10.1192/bjp.bp.114.155945 PubMed PMID: PubMed PMID: 25934299. Current status of clozapine in the United States. For more information about this change, call the Clozapine REMS Transition Contact Center at 1-888-586-0758 or visit the Clozapine REMS website. Q3. Why did the FDA approve this modification to the Clozapine REMS? Q5. What actions do prescribers need to take to continue to participate in the new Clozapine REMS? Symptoms of schizophrenia include hearing voices or seeing things that are not there and being suspicious or withdrawn. Practice guideline for the treatment of patients with schizophrenia. [PubMed] [CrossRef] [Google Scholar] On July 29, 2021, FDA approved modifications to the Clozapine Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of the drug outweigh the risk of severe neutropenia. 28758583 DOI: 10.2174/1871527316666170728165355 PubMed PMID: PubMed PMID: 28758583. 2010;36(1):71-93. Lilly J, Gaughran F, Timms P, Curran S. Clozapine is an antipsychotic drug used to help improve the symptoms of schizophrenia in patients who do not respond adequately to standard antipsychotic treatment. For inpatient use, pharmacies will continue to obtain an RDA (previously called PDA) prior to the initial dispensing. Q1. 25324612 DOI: 10.3969/j.issn.1002-0829.2012.02.007 PubMed PMID: PubMed PMID: 25324612. doi: 10.1176/appi.app.163.4.600. New trends in the treatment of schizophrenia. Arch Gen Psychiatry. Side-effects and treatment with clozapine: a comparison between the views of consumers and their clinicians. Q4. What should patients know about the new requirements in the Clozapine REMS program? Taylor M, Perera U. 2014;130(1):16-24. Q8. Psychiatr Bull. Taylor D, Shapland L, Laverick G, Bond J, Munro J, Conley RR, Tamminga CA, Kelly DL, Richardson CM. Changes were also made to improve the process for a prescriber to submit absolute neutrophil count (ANC) results. Nielsen J, Dahm M, Lublin H, Taylor D. 24004162 DOI: 10.1111/acps.12193 PubMed PMID: PubMed PMID: 24004162. 1988;45(9):789-96. [PubMed] [CrossRef] [Google Scholar]9. 24233347 DOI: 10.1176/appi.ps.201300180 PubMed PMID: PubMed PMID: 24233347. PubMed PMID: 10394475. 9524789 DOI: 10.1185/03079979113338 PubMed PMID: PubMed PMID: 9524789. The Patient Status Form is used to document the patient's ANC results, monitoring frequency, and appropriateness to continue treatment.

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