



Clozapine: Care of Patient Receiving (Mental Health)

Site Applicability

Providence Health Care (PHC):

- St. Paul's Hospital: Acute Psychiatric Units (2E/PASU, 2N, 8C, 9A)
- Mount St. Joseph Hospital: Geriatric Psychiatry Unit (MSJ-1S)
- St. Vincent's Langara: Alder Neuropsychiatry Unit
- Youville: Parkview Unit

Vancouver Coastal Health (VCH):

• Vancouver General Hospital: Segal 5, 6, 7, 8, PAU, PEAT

Practice Level

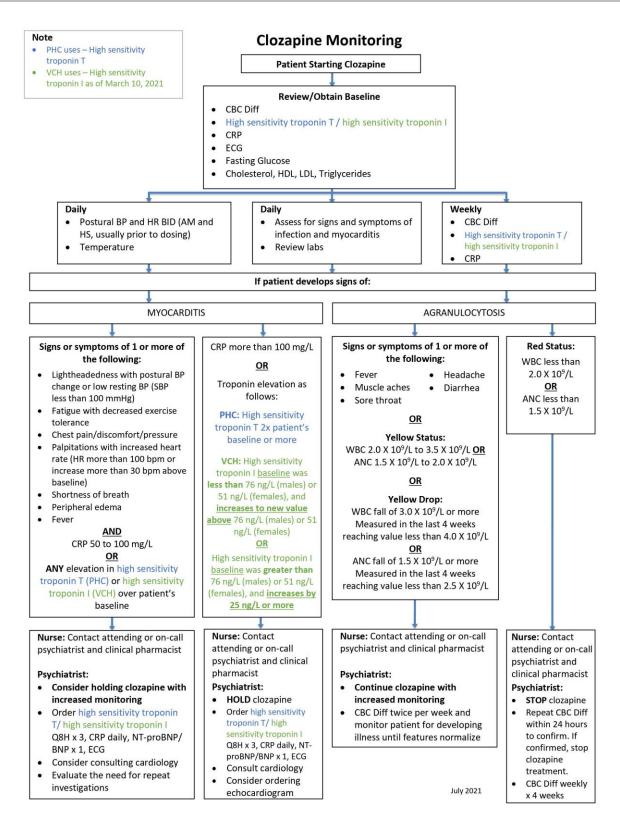
- RN/RPN
- Pharmacist
- Physician

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Need to Know

Clozapine is typically reserved for treatment-resistant or treatment-intolerant schizophrenia. Although an effective antipsychotic agent, the use of clozapine has been associated with severe adverse effects, including myocarditis and agranulocytosis. The literature demonstrates a clear need to implement close and structured monitoring of patients on clozapine to prevent the development of serious adverse outcomes.

Terminology:

New Start: Ordering clozapine for a patient never prescribed clozapine in the past.

Restart: Re-ordering clozapine for a patient who has missed doses for two or more days OR if medication compliance is unknown.

Continuation: Ordering clozapine consistent with treatment prior to hospitalization, where treatment has been uninterrupted (i.e. patient has not missed doses for two or more days).

Clozapine New Start

- For new starts, the physician and pharmacist will complete, sign, and fax a clozapine registration form with preliminary complete blood count with differential (CBC Diff) results to one of the clozapine manufacturers/monitoring programs (Gen-Clozapine/GenCAN, AA-Clozapine/AASPIRE, Clozaril/CSAN).
- Registration forms can be obtained from www.gencan.ca, www.aaclozapine.ca, www.csan.ca
- The manufacturer will provide a registration number within 48 business hours.
- The pharmacist will enter the registration number in the patient's medication profile.

Clozapine Restart

- For restarts, the physician is to determine which drug manufacturer the patient was previously registered with and complete the corresponding registration form (see above)
- If the patient is still registered with the company then check off the "modify/modification" box on the form and update the Most Responsible Physician (MRP) information. Under the 'Pharmacy' and 'Lab" sections, provide the name of our institution (i.e., St. Paul's Hospital). In this case, the patient can continue re-titration immediately.
- The pharmacist will enter the registration number in the patient's medication profile if it is not already there.
- If the patient is restarting after a longer period of time and are no longer enrolled with the company, then follow same steps as for a "new start"

Clozapine Continuation

• For continuations, the physician is to determine the drug manufacturer the patient was previously registered with and complete the corresponding registration form.

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Check off the "modify/modification" box on the form and update the Most Responsible
 Physician (MRP) information. Under the 'Pharmacy' and 'Lab' sections, provide the name of our
 institution (e.g. St. Paul's Hospital).

Clozapine Manufacturer Information

	Website	Telephone	After hours telephone	Fax	
Genpharm			1-866-501-3338,		
(GenCAN)	www.gencan.ca	1-866-501-3338	request to speak to a	1-800-497-9592	
			nurse		
AA Pharma		4 077 276 2560	1-877-276-2569, leave	4 000 000 0770	
(AASPIRE)	www.aaclozapine.ca	1-877-276-2569	a message	1-866-836-6778	
Clozaril			1-800-267-2726,	1-604-689-1262	
	www.csan.ca	1-800-267-2726	request to speak to a	(BC only) OR	
(CSAN)			nurse	1-800-465-1312	

Pre-Printed Orders (PPOs)

Once approved by a clozapine manufacturer and a registration number is provided, the MRP is to complete the Clozapine PPO (PHC (Power Chart): MH cloZAPine Monitoring* or VCH: VCH.VA.PPO.1049). CBC Diff results should be within normal limits before starting, restarting or continuing clozapine.

Protocol

Assessment and Interventions

Baseline Assessment

As outlined in the Clozapine PPO, the following tests are ordered to establish patient's baseline:

- 1. CBC Diff
- 2. C-Reactive Protein (CRP)
- 3. Troponin

PHC: high sensitivity troponin T **VCH**: high sensitivity troponin I

- 4. Electrocardiogram (ECG)
- 5. Fasting glucose
- 6. Fasting cholesterol, HDL, LDL, triglycerides
- 7. Vital signs

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^{*}The MRP may initiate the MH cloZAPine Pre-Treatment module for clozapine new starts; medications can be ordered using the MH clozapine qdaily/q2day/q3day Titration Power Plans respectively, or ad hoc.





Ongoing Assessment

While patients are on clozapine, ongoing assessment includes:

- Vital signs:
 - o Postural blood pressure (BP), heart rate (HR) BID (AM and HS)
 - Temperature daily
- Daily assessment for signs and symptoms of potential infection or myocarditis:
 - Lightheadedness with concomitant postural BP change or low resting BP (i.e. SBP less than 90 mmHg)
 - Fatigue with decreased exercise tolerance
 - Chest pain/ discomfort/ pressure
 - Palpitations with increased heart rate HR more than 100 bpm or 30 bpm above the patient's baseline.
 - Shortness of breath
 - Peripheral edema
- Weekly, biweekly, or monthly CBC Diff, depending on patient's monitoring protocol registered with the manufacturer (with results faxed to monitoring company), and weekly CRP and troponin for the first four weeks of treatment.
- Daily review of lab results (white blood cells (WBC), neutrophils (ANC), CRP and troponin by nursing staff)

Interventions

Nurses should report the following findings to the MRP and clinical pharmacist:

- Signs and symptoms of myocarditis (as outlined in ongoing assessment, see algorithm)
- Signs and symptoms of infection (as outlined in ongoing assessment, see algorithm)
- WBC and ANC results in the yellow, yellow drop or red zones
- CRP greater or equal to 50 mg/L
- Troponin
 - o **PHC**: clinically relevant elevation in high-sensitivity troponin T, see algorithm)
 - VCH: clinically relevant elevation in high-sensitivity troponin I, see algorithm)

See <u>Clozapine Monitoring algorithm</u> for interventions related to the above findings. This algorithm is also located on the clozapine PPO and clozapine Monitoring Flowsheet.

Documentation

Nurses document ongoing assessments and review of lab results on the **Clozapine Monitoring Flowsheet** (PHC: Power Chart \rightarrow Interactive View and I&O \rightarrow MH Evaluation Tools \rightarrow Clozapine
Monitoring or VCH: VCH.VA.VGH.0826). Additional notes can be added in the interdisciplinary progress notes of the patient's chart.

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Related Documents

- 1. Lexicomp Online Drug Reference
- 2. Clozapine Pre-Printed Orders:
 - o PHC: MH cloZAPine Monitoring
 - o VCH: VCH.VA.PPO.1049
- 3. Clozapine Monitoring Flowsheet
 - PHC: Power Chart → Interactive View and I&O → MH Evaluation Tools → Clozapine Monitoring
 - o VCH: VCH.VA.VGH.0826
- 4. <u>Discharge Summary Fax to Community</u> (VCH: BCHA.0101)
- 5. Clozapine Patient Handout (FH Catalogue #265989, patienteduc.fraserhealth.ca)

References

- Caforio, A. L., Pankuweit, S., Arbustini, E., et al. (2013). Current state of knowledge on aetiology, diagnosis, management, and therapy of myocarditis: a position statement of the European Society of Cardiology Working Group on Myocardial and Pericardial Diseases. European Heart Journal, 34, 2636-2648.
- 2. De Berardis, D., Serroni, N., Campanella, D., Olivieri, L., Ferri, F., Carano, A., et al. (2012). Update on the adverse effects of clozapine: focus on myocarditis. Current Drug Safety, 7(1), 55-62.
- 3. Mahrholdt, H., Wagner, A., Deluigi, C.C., et al. (2006). Presentation, patterns of myocardial damage, and clinical course of viral myocarditis. Circulation, 114, 1581-1590.
- 4. Murch, S., Tran, N., Liew, D., Petrakis, M., Prior, D., & Castle, D. (2013). Echocardiographic monitoring for clozapine cardiac toxicity: lessons from real-world experience. Australasian Psychiatry, 3, 258-26.
- 5. Ronaldson, K. J., Fitzgerald, P. B., & McNeil, J. J. (2015). Clozapine-induced myocarditis, a widely overlooked adverse reaction. Acta Psychiatrica Scandinavica.
- Ronaldson, K. J., Fitzgerald, P. B., Taylor, A. J., Topliss, D. J., & McNeil, J. J. (2011). A new monitoring protocol for clozapine-induced myocarditis based on an analysis of 75 cases and 94 controls. Australian and New Zealand Journal of Psychiatry, 45(6), 458-465.
- 7. Smith, S.C., Ladenson, J.H., Mason, J.W., & Jaffe, A.S. (1997). Elevations of cardiac troponin I associated with myocarditis experimental and clinical correlates. Circulation, 95(1),163-165.

Persons/Groups Consulted

Pharmacy and Therapeutics Committee, PHC & VCH Psychiatrists, Segal Centre, VCH Clinical Pharmacist, Cardiology, PHC Clinical Nurse Educator, Segal Centre, VCH

Staff Nurses: SPH & Segal Centre

Clinical Nurse Specialist, Tertiary & Older Adult Mental Health, PHC

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Date of Creation/Review/Revision

January 2016

Revised: February 2016

April 2016 July 2018 Nov 2018 July 2021

Oct 27, 2021- Troponin updated on algorithm

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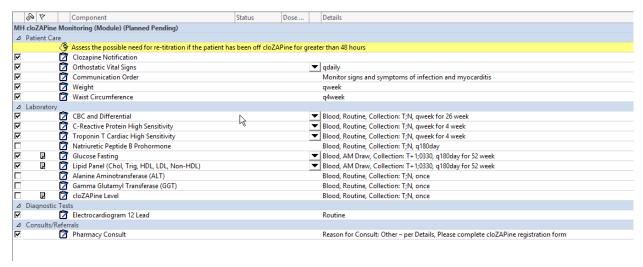
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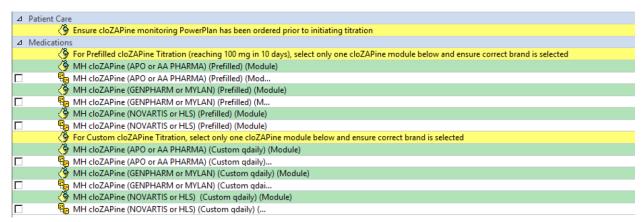


Appendix A:

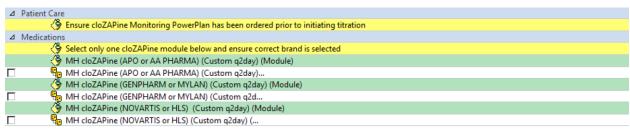
Clozapine Power Plan (MH cloZAPine Monitoring)



Clozapine Power Plan (MH cloZAPine qdaily Titration)



Clozapine Power Plan (MH cloZAPine q2day Titration)



Note: the MH cloZAPine q3day Titration Power Plan will specify "Custom q3day" respectively

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1049



PROTOCOL BD-00-13-40100

Psychiatry Clozapine Pre-printed Order VCH (VCH.VA.PPO.1049)

IF YO	OU RECEIVED THIS FACSIMILE IN ERRO	R, PLEASE CALL 604-875-4077 IMMEDIA	TELY				
Vancouve Coastall VA: VGH / UBC VC: BP / Purdy	Health H/GFS	ADDRESSOGRAPH					
	COMPLETE OR REVIEW ALLERGY S	TATUS PRIOR TO WRITING ORDERS					
	Psychiatry Clo	zapine Orders					
	(items with check boxes must		(Page 1 of 2)				
Date:	Date: Time:						
RESTRICTIO	DNS: this order set is to be used only in the Segal	Centre on Floors 5-8 and in VGH PAU/PEAT					
seizure, sign Patient adhe	on ordering clozapine should be aware of the potential ifficant hypotension, and agranulocytosis associated or or or or or or order assessment should include the following: Phare	with clozapine starts and restarts.					
from team/fa	cility and patient reporting.						
ASSESSMENT:	New Start or Restart (non-adherent for 2 or mo Pharmacist and Psychiatrist to complete Cloze (GenPharm, AA Pharma, or CSAN; see re	apine Registration Form					
	OR						
		10 .					
	☐ clozapine continuation (patient adi 🤋 २n with	satment or non-adherent for less than 2 days)					
	Adherence confirmed by: Con munity Pha	armacy Housing					
	Mental Health	「eam ☐ Other:					
	Brand a ic R ag st. ation Number: AA-Pharm	a (AASPIRE) #					
	Genpharm						
	☐ Clozaril (C	SAN) #					
	Clozapine will only be supplied by pharmacy once registration number and/or an approval to start by obseline CBC Diff is within normal limits before sta	one of the 3 drug companies. Please ensure					
MONITORING:	Document on Clozapine Monitoring Flowsheet (VC	H.VA.VGH.0826)					
	Postural BP and HR BID (AM and HS)	,					
	Temperature daily						
	Monitor for signs of infection and myocarditis; see	reverse for details					
LABORATORY:	Only order fasting glucose and lipid tests if not alr	eady done in the past 3 months.					
	CBC diff baseline then Q Tuesday (Lab fax results	· ·					
	CRP and high sensitivity troponin I baseline then C	Tuesdays x 4 weeks					
	Fasting glucose						
	Fasting cholesterol, HDL, LDL, triglycerides						
DIA ONO TION	500						
DIAGNOSTICS:	ECG						
Prescriber's Sign	nature Printed Name VCH.VA.PPO.1049 Rev	College ID v.APR.2021					

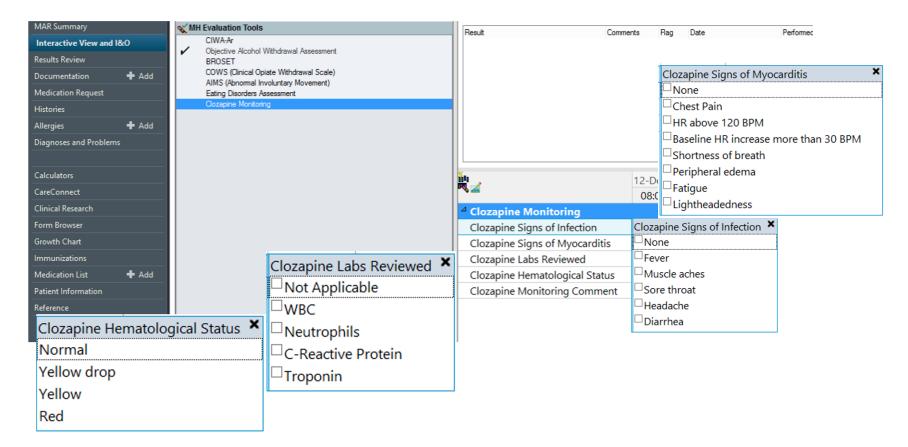
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Appendix B: Clozapine Monitoring in Power Chart



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Clozapine Monitoring Flowsheet VGH (VCH.VA.VGH.0826)

Vancouver Coastal Health Vancouver General Hospital	PCIS Label
CLOZAPINE MONITORING FLOWSHEET	

VITALS SIGNS - Document on Vital Signs Sheet (VCH-M-37). Postural BP and HR BID (AM and HS)

		Mor	nday	Tue	sday	Wedn	esday	Thur	sday	Fri	day	Saturday		Sunday		
	Date:															
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	
	Times:															
	DRATORY (Q shift)															
Blood	lwork drawn today	□ No		☐ No ☐ Yes (document below)		☐ No ☐ Yes (document below)		☐ N0 ☐ Yes (document below)		□ No		☐ No ☐ Yes (document below)		□ No		
WBC		☐ Yes (doc		☐ Yes (doc		☐ Yes (doc		☐ Yes (doc		☐ Y S (dc		☐ Yes (do	,			
			_ x 10 ⁹ /L		x 10 ⁹ /L		_ x 10 ⁹ /L		x 10 ⁹ /L		_ x 10 ⁹ /L		x 10 ⁹ /L	x 10 ⁹ /L		
Neutr	ophils (ANC)		x 109/L		x 109/L		x 109/L		× 1L 9/		x 109/L		x 10 ⁹ /L		x 10 ⁹ /L	
Hema	atological Status	□ Nomal □	Yellow Drop	☐ Normal ☐ Yellow Drop		□ Normal □ Yellow Drop				□ Nomal □	□ Normal □ Yellow Drop		□ Normal □ Yellow Drop		☐ Normal ☐ Yellow Drop	
		☐ Yellow ☐ Red		☐ Yellow ☐ Red		☐ Yellow ☐ Red		□ Yellor □ Rec		☐ Yellow ☐ Red		□ Yellow □ Red		☐ Yellow ☐ Red		
								I IU								
	ference, see reverse for he active protein (CRP)	ematologic st		na ciozapine i		wcnart	-							1		
		mg/L			mg/L		119_1	mg/L		mg/L		mg/L		mg/L		
High	sensitivity troponin I		ng/L	ng/L			ny/L	ng/L			ng/L	g/Lng/L		ng/L		
	Nurse Initial:															
MON	ITORING (Q shift) ✓=	Infection o	r myocardit	is symptom	DI SE IL L.	cument int	erventions i	n Progress	Notes.							
	Fever				M.											
-	Muscle aches				- 1											
Infection	Sore throat			70.												
lufe	Headache															
	Diarrhea															
	None															
	Chest pain															
	HR above 100 bpm															
.s	HR 30 bpm above baseline															
Myocarditis	Shortness of breath															
yoc	Peripheral edema															
Σ	Fatigue															
	Light-headedness															
	None															
Constipation		□No		□ No		□No		□No		□No		□No		□No		
(Indicate current day of		☐ Yes (Day 1 ☐,		☐ Yes (Day 1 ☐,		☐ Yes (Day 1 ☐,		☐ Yes (Day 1 ☐,		☐ Yes (Day 1 ☐,		☐ Yes (Day 1 ☐,		☐ Yes (Day 1 ☐,		
bowe	I protocol treatment)	Day 2 □,		Day 2 □,		Day 2 □,		Day 2 □,		Day 2 □,		Day 2 □,		Day 2 □,		
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	Nurse Initial:		1		1	1	I			1	l	1	1		1	

VCH.VA.VGH.0826 | APR.2021

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Appendix C: VCH-PHC Discharge Summary to Community (BCHA.0101TRIAL)





CLOZAPINE DISCHARGE SUMMARY FAX TO COMMUNITY

Patient demographics

	completed by Hospital Phanagement Leader (VCH)				
TO:	Mental Health Team	Pharmacy		cloZAPine Program	
FAX	:				
FROM	1:			•	
	Hospital	Unit	Phone	FAX	
This clie	ent is being discharged fron	n	ame of Hospital	on	
CLOZA	PINE DOSE & BRAND AT	DISCHARGE (no	substitution):	, 1150	
CLOZA	PINE MONITORING PRO	GRAM:	-	401	
CLIEN	IT ID #:			100	
BLOC	DWORK: (CBC with di	fferential)	111/20		
Freque	ncy of bloodwork: 🔲 we	ekly 🗌 every	v ′e ek □ every 4	weeks	
Last blo	oodwork completed: (date)		Re	sult:	
Next blo	oodwork due: (date)	no lo	They plan to go to $_$		lab for this.
BEFO • •	Call their Lab to c is firm bl	oodwork was draw onitoring program to ore they receive th	n o determine if the blo nese results.)	s had their blood work doodwork results have been redwork was drawn	
	APINE MAY ONLY BE NE week's supply if they are		· ·	s <u>until</u> their next bloodwork is o	due
Physic 1) Coccle 2) Co Commo	oZÀPine program. omplete laboratory requisition unity Pharmacist:	manager section on for standing blo	on the Patient Regis odwork and fax cop	tration form and fax to approp y to lab. o appropriate cloZAPine progr	
	E CONTACT ME WITH AN				
Pharma	acist:		Hospital:		
	01TRIAL NOV.2018				Page 1 of 1

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Appendix D: Clozapine Patient Handout

Clozapine - continued What should I look out for? Here are some possible side effects and what to do if you notice them Clozapine (say klo-za-peen) non Side Effects Rare but Serious Side Effects What is clozapine? How quickly will it start working? a) Constipation a) Low number of white blood cells Some of your symptoms might get better before others.

Over the first few weeks, you might find that you sleep better and have fewer mood changes. This medicine is a type of antipsychotic (say an-tee-sy-kot-ick). This is a very common side effect. Ask your doctor and/or pharmacist if you should time fighting off infections (called neutropenia - say new-tro It is most commonly used to treat symptoms of psychosis (ear sigh-to-stal) such as hearing voices or false beliefs.
Psychosis can occur in different types of illnesses such as schizophrenia and bipolar disorder. b) Blurred vision

Can happen in the first 1 to 2 weeks and should go away over time. Over the next 2 to 8 weeks, hallucinations or delusions fade away and your thoughts become clearer. Clozapine can also be used to treat other types of illnes · Other symptoms like having no interest in yourself or If the blurred vision does not get better, speak to the right amount of clozapine. (such as mania) without psychosis others might continue to get better over 6 months or more. Example of blood test schedule: your doctor and/or pharmacist Clozapine is often used when other antipsychotics do not Once every week for the first 6 months
Once every 2 weeks for the next 6 months How do I take clozapine? c) Dizziness work or cause intolerable side effects Take your time getting up from a sitting or Take clozapine regularly as prescribed. You are taking this medicine for: Once every 4 weeks after 1 year Schizophrenia · You can take it with or without food. Watch for symptoms of infection such as a fever, sore throat, ☐ Bipolar Disorder . If you miss a dose take it as soon as possible and other symptoms that feel like you are getting the flu. d) Drooling · If it is almost time for your next dose, skip the missed Other: b) Myocarditis and cardiomyopathy Mostly happens at night. dose and return to your regular schedule Do not take 2 doses at the same time. Clozapine can cause a rare allergic reaction involving your heart muscle (called myocarditis – say my-oh-card-eye-tis). Use a small towel on the pillow when sleeping How does clozapine work? Talk to your doctor and/or pharmacist If this continues to be bothersome. If you miss more than 2 days of clozapine tell your Schizophrenia, bipolar disorder, and other types of doctor and/or pharmacist right away. You will ne restart the clozapine at a lower dose and slowly increased back to your current dose. illnesses can happen when the chemicals in your brain are out-of-balance. specially when you begin clozapine Clozapine can rarely cause your heart muscles to become Always take this medicine at bedtime to reduce Clozapine works by restoring the balance of the brain's chemicals. This can help reduce:

Hallucinations - feeling unusual body sensations; hearing, seeing, smelling or tasting things that are not real daytime drowsiness. Caution: It is dangerous to drive or operate machinery when drowsy Why is it important to keep taking it? f) Weight gain Choose healthy foods and exercise regularly Always take the amount you are supposed to take (the dose written on the prescription label).
Do not change how much you take. ng tired all the time. Delusions - feeling that someone is following you or trying Drink water, instead of "Agay be "rabe" g) Increase of less to and/or blood sugar Yo "do to nord" your cholesterol and blood sug an... iss your medicines as needed. Heat, I tooks and exercise can help decrease cholesterol and blood sugar. c) Seizures to hurt you; feeling that people are talking about you; or Do not stop taking it without talking to your doctor. feeling that you have special powers or are famous Tell your doctor right away if you have had seizures in the If you do not take it as prescribed, the amount of past, and/or if you have any new seizures or black-outs. Clozanine can also: clozapine in your body can get too low, making it not d) Neuroleptic Malignant Syndrome

Any antipsychotic can cause this very rare side effect. help improve your mood work as well to treat your symptoms and increase the help you sleep better nces of side effects. Symptoms include a very high fever, sweating, fast heartbeat, breathing fast, changes in blood pressure, rigid or stiff muscles, and confusion. help you have less unusual body movements caused by other antipsychotic medicines called extrapyramidal (say extra-per-ah-mid-help you feel calmer and less fearful While this medicine has more side effects and more blood tests than other antipsychotics, it is important to continue taking it. Clozapine is a very help you have less harmful thoughts
 help you think more clearly and concentrate better effective medicine for psychosis. fraserhealth Providence

Clozapine - continued

When should I get help?

- See your doctor as soon as possible if:

 Your symptoms of psychosis are getting worse
- · You are feeling hopeless, or you feel that there is no way to solve the problem or end the pain · Any of the common side effects do not go away or
- · You notice any symptoms of infection such as a fever
- Go to the nearest Emergency Department if:

 You feel like acting on thoughts of harming yourself
- You feel very sick like you have the flu.

What else should I know?

Other medicines can change how clozapine works.

Always check with your doctor and/or pharmacist before taking any other medicines, including prescription, ove the-counter and herbal medicines.

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Smoking cigarettes and/or cannabis can lower the amount of clozapine in your body. Tell your doctor and/or pharmacist if you smoke, stop smoking, or change how much you smoke.

take the same brand of clozapine every day. Talk to your pharmacist right away if you are given a different brand of clozapine than before.

When you have less white blood cells, your body has a harde

Your doctor sends you for regular blood tests so this problem can be caught before it becomes a serious problem. Always get your blood tests done as scheduled so your pharmacy can give you

You might need to have regular blood tests to check for this

weaker (called cardiomyopathy - say card-ee-oh-my-op-ah-thee).
This can happen months to years after starting clozapine. Watch for symptoms such as chest pain, shortness of breath racing heartbeat, severe headache, general muscle pain, and

This information does not replace the advice given to you by your healthcare provider March 2019

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- Call 9-1-1 if you have:

 Any chest pain or problems breathing.
- · Any symptoms of neuroleptic malignant syndrome

It is important to get your blood tests on time to make sure you do not have neutropenia. If you do not get your blood test, your pharmacy might not give you more clozapine

Clozapine comes in different brands. It is important to

It's good to ask questions

Anytime you have any questions or concerns about taking this medicine, talk with one of your healthcare team. Of the second sec

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