

# CLOZAPINE REMS

## The Single Shared System for Clozapine No Blood, No Drug™

### Recommended Monitoring Frequency and Clinical Decisions by ANC Level

ANC Level	Treatment Recommendation	ANC Monitoring
<p><b>Normal Range for a New Patient</b></p> <ul style="list-style-type: none"> <li>General Population (ANC <math>\geq</math> 1500/<math>\mu</math>L)</li> </ul> <p><b>BEN POPULATION</b></p> <ul style="list-style-type: none"> <li>BEN Population (ANC <math>\geq</math> 1,000/<math>\mu</math>L)</li> <li>Obtain at least two baseline ANC levels before initiating treatment</li> </ul>	<ul style="list-style-type: none"> <li>Initiate treatment</li> <li>If treatment interrupted: <ul style="list-style-type: none"> <li>&lt; 30 days, continue monitoring as before</li> <li><math>\geq</math> 30 days, monitor as if new patient</li> </ul> </li> <li>Discontinuation for reasons other than neutropenia</li> </ul>	<ul style="list-style-type: none"> <li>Weekly from initiation to 6 months</li> <li>Every 2 weeks from 6 to 12 months</li> <li>Monthly after 12 months</li> <li>See Section 2.4 of the full Prescribing Information</li> </ul>
<p><b>Mild Neutropenia</b> (1000 to 1499/<math>\mu</math>L)*</p>	<p><b>GENERAL POPULATION</b></p> <ul style="list-style-type: none"> <li>Continue treatment</li> </ul>	<p><b>GENERAL POPULATION</b></p> <ul style="list-style-type: none"> <li>Three times weekly until ANC <math>\geq</math> 1500/<math>\mu</math>L</li> <li>Once ANC <math>\geq</math> 1500/<math>\mu</math>L, return to patient's last "Normal Range" ANC monitoring interval**</li> </ul>
	<p><b>BEN POPULATION</b></p> <ul style="list-style-type: none"> <li>Mild Neutropenia is normal range for BEN population, continue treatment</li> <li>Obtain at least two baseline ANC levels before initiating treatment</li> <li>If treatment interrupted <ul style="list-style-type: none"> <li>&lt; 30 days, continue monitoring as before</li> <li><math>\geq</math> 30 days, monitor as if new patient</li> </ul> </li> <li>Discontinuation for reasons other than neutropenia</li> </ul>	<p><b>BEN POPULATION</b></p> <ul style="list-style-type: none"> <li>Weekly from initiation to 6 months</li> <li>Every 2 weeks from 6 to 12 months</li> <li>Monthly after 12 months</li> <li>See Section 2.4 of the full Prescribing Information</li> </ul>
<p><b>Moderate Neutropenia</b> (500 to 999/<math>\mu</math>L)*</p>	<p><b>GENERAL POPULATION</b></p> <ul style="list-style-type: none"> <li>Recommend hematology consultation</li> <li>Interrupt treatment for suspected clozapine induced neutropenia</li> <li>Resume treatment once ANC normalizes to <math>\geq</math> 1000/<math>\mu</math>L</li> </ul>	<p><b>GENERAL POPULATION</b></p> <ul style="list-style-type: none"> <li>Daily until ANC <math>\geq</math> 1000/<math>\mu</math>L, then</li> <li>Three times weekly until ANC <math>\geq</math> 1500/<math>\mu</math>L</li> <li>Once ANC <math>\geq</math> 1500/<math>\mu</math>L, check ANC weekly for 4 weeks, then return to patient's last "Normal Range" ANC monitoring interval**</li> </ul>
	<p><b>BEN POPULATION</b></p> <ul style="list-style-type: none"> <li>Recommend hematology consultation</li> <li>Continue treatment</li> </ul>	<p><b>BEN POPULATION</b></p> <ul style="list-style-type: none"> <li>Three times weekly until ANC <math>\geq</math> 1000/<math>\mu</math>L or <math>\geq</math> patient's known baseline.</li> <li>Once ANC <math>\geq</math> 1000/<math>\mu</math>L or patient's known baseline, then check ANC weekly for 4 weeks, then return to patient's last "Normal BEN Range" ANC monitoring interval**</li> </ul>
<p><b>Severe Neutropenia</b> (less than 500/<math>\mu</math>L)*</p>	<p><b>GENERAL POPULATION</b></p> <ul style="list-style-type: none"> <li>Recommend hematology consultation</li> <li>Interrupt treatment for suspected clozapine induced neutropenia</li> <li>Do not rechallenge unless prescriber determines benefits outweigh risks</li> </ul>	<p><b>GENERAL POPULATION</b></p> <ul style="list-style-type: none"> <li>Daily until ANC <math>\geq</math> 1000/<math>\mu</math>L</li> <li>Three times weekly until ANC <math>\geq</math> 1500/<math>\mu</math>L</li> <li>If patient rechallenged, resume treatment as a new patient under "Normal Range" monitoring once ANC <math>\geq</math> 1500/<math>\mu</math>L</li> </ul>
	<p><b>BEN POPULATION</b></p> <ul style="list-style-type: none"> <li>Recommend hematology consultation</li> <li>Interrupt treatment for suspected clozapine induced neutropenia</li> <li>Do not rechallenge unless prescriber determines benefits outweigh risks</li> </ul>	<p><b>BEN POPULATION</b></p> <ul style="list-style-type: none"> <li>Daily until ANC <math>\geq</math> 500/<math>\mu</math>L</li> <li>Three times weekly until ANC <math>\geq</math> patient's established baseline</li> <li>If patient rechallenged, resume treatment as a new patient under "Normal Range" monitoring once ANC <math>\geq</math> 1000/<math>\mu</math>L or at patient's baseline</li> </ul>

\* Confirm all initial reports of ANC less than 1500/ $\mu$ L (ANC < 1000/ $\mu$ L for BEN patients) with a repeat ANC measurement within 24 hours

\*\* If clinically appropriate