

**Ziprasidone Mesylate for Injection, 20 mg/mL**

S.No.	Category	Question	Answer
<b>Clinical Particulars</b>			
1.	Use/Indication	What is the product indicated for?	<p>Ziprasidone mesylate for injection is an atypical antipsychotic. In choosing among treatments, prescribers should be aware of the capacity of ziprasidone mesylate for injection to prolong the QT interval and may consider the use of other drugs first.</p> <p>Ziprasidone mesylate for injection as an intramuscular injection is indicated for the:</p> <ul style="list-style-type: none"> <li>• Acute treatment of agitation in schizophrenic patients.</li> </ul>
2.	Dosage	What is the recommended dosage?	<p>For Acute Treatment of Agitation in Schizophrenia, the recommended dose is 10 mg to 20 mg administered as required up to a maximum dose of 40 mg per day.</p> <p><i>Please refer to Prescribing Information for complete details.</i></p>
3.	Administration	How do I take?	As prescribed by the physician.
4.	Side effects	What are the most common and possible side effects?	<p>Commonly observed adverse reactions were:</p> <ul style="list-style-type: none"> <li>• Schizophrenia: Somnolence, respiratory tract infection.</li> <li>• Manic and Mixed Episodes Associated with Bipolar Disorder: Somnolence, extrapyramidal symptoms, dizziness, akathisia, abnormal vision, asthenia, vomiting.</li> <li>• Intramuscular administration (≥5% and at least twice the lowest intramuscular ziprasidone group): Headache, nausea, somnolence.</li> </ul>
5.	Administration	Use in Pediatric Population	The safety and effectiveness of ziprasidone in pediatric patients have not been established.
6.	Administration	Use in Geriatric Population	<p>No overall differences in safety or effectiveness were observed between geriatric patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.</p> <p>Nevertheless, the presence of multiple factors that might increase the pharmacodynamic response to ziprasidone, or cause poorer tolerance or orthostasis, should lead to consideration of a lower starting dose, slower titration, and careful monitoring during the initial dosing period for some elderly patients.</p>
7.	Mechanism	Mechanism of Action	The mechanism of action of ziprasidone in the treatment of the listed indications could be mediated through a combination of dopamine type 2 (D) and serotonin type 2 (5HT) antagonism.
8.	Warning	Black Box Warning	<b>INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS</b>

			<i>Please refer to Prescribing Information for complete details .</i>
9.	Lactation	Use in Lactation	<p>The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for ziprasidone mesylate for injection and any potential adverse effects on the breastfed child from ziprasidone or from the mother’s underlying condition.</p> <p>Breastfeeding women using ziprasidone mesylate for injection are advised to monitor infants for excess sedation, irritability, poor feeding, and extrapyramidal symptoms (tremors, and abnormal muscle movements) and to seek medical care if they notice these signs.</p>
10.	Pregnancy	Use in Pregnancy	<p>Pregnant women are advised to notify their healthcare provider if they become pregnant or intend to become pregnant during treatment with ziprasidone mesylate for injection.</p> <p>Patients should be advised that ziprasidone mesylate for injection may cause extrapyramidal and/or withdrawal symptoms (agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress, and feeding disorder) in a neonate.</p>
11.	Storage	What are the storage conditions?	Ziprasidone mesylate for injection should be stored at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) in dry form. Protect from light. Following reconstitution, ziprasidone mesylate for injection can be stored, when protected from light, for up to 24 hours at 15°C to 30°C (59°F to 86°F) or up to 7 days refrigerated, 2°C to 8°C (36°F to 46°F).
12.	Dispensing	How to Dispense?	As prescribed by the Physician
13.	Contraindication	What are the contraindications of (medication)?	<p>Contraindicated in patients with</p> <ul style="list-style-type: none"> <li>• known history of QT prolongation (including congenital long QT syndrome)</li> <li>• recent acute myocardial infarction.</li> <li>• uncompensated heart failure.</li> </ul> <p><i>Please refer to Prescribing Information for complete details.</i></p>
<b>Miscellaneous</b>			
14.	Miscellaneous	May I know the product availability?	Novadoz Pharmaceuticals products are only available through pharmacies, wholesalers, and other authorized distributors. See our ADR (authorized distributors of record) page at NovadozPharma.com to learn more about where to find our products
15.	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
16.	Miscellaneous	Do you have any patient's assistance program?	Novadoz Pharmaceuticals does not offer patient assistance programs at this time. The company that produces the brand version of your product may or may not offer such a program. Please check for access & eligibility requirements with that company
17.	Miscellaneous	Why does my pharmacy, that used to fill your generic formulation of a particular medicine,	Please check with your pharmacy as to why your prescription is not a Novadoz Pharmaceuticals product. You may refer to NovadozPharma.com ADR (authorized distributor of record) page to learn where to find our products

		no longer fills my prescription with Novadoz formulation?	
18.	Miscellaneous	May I know where is this product manufactured?	<p><b>Manufactured by:</b> MSN Laboratories Private Limited Telangana – 509 228, INDIA</p> <p><b>Distributed by:</b> Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714 TEL: 855-NOVADOZ (668-2369)</p>