

FLUPHENAZINE DECANOATE INJECTION USP 125 mg/5 mL (25 mg/mL) Multiple-Dose Vials

S.No.	Category	Question	Answer
Clinical Particulars			
1.	Use/Indication	What is the product indicated for?	<p>1. Fluphenazine Decanoate Injection is a long-acting parenteral antipsychotic drug intended for use in the management of patients requiring prolonged parenteral neuroleptic therapy (e.g., chronic schizophrenics).</p> <p><i>Fluphenazine Decanoate Injection has not been shown effective in the management of behavioral complications in patients with mental retardation.</i></p>
2.	Dosage	What is the recommended dosage?	<p>1. Initial Dose:</p> <ul style="list-style-type: none"> • For most patients: 12.5 to 25 mg (0.5 to 1 mL). • Onset of action: 24-72 hours, with significant effects on psychotic symptoms within 48-96 hours. <p>2. Maintenance Therapy:</p> <ul style="list-style-type: none"> • Single injection may control symptoms for up to 4 weeks, potentially 6 weeks in some patients. <p>3. Initial Therapy for Naive Patients:</p> <ul style="list-style-type: none"> • Start with a shorter-acting fluphenazine to assess response before switching to decanoate. <p>4. Conversion from Oral Fluphenazine:</p> <ul style="list-style-type: none"> • 20 mg daily of Fluphenazine Hydrochloride \approx 25 mg (1 mL) of Fluphenazine Decanoate every 3 weeks. • Approximate ratio: 12.5 mg (0.5 mL) decanoate for every 10 mg oral daily dose. <p>5. Severely Agitated Patients:</p> <ul style="list-style-type: none"> • Start with a rapid-acting phenothiazine, then follow with 25 mg (1 mL) of Fluphenazine Decanoate. <p>6. Dosage Adjustments:</p> <ul style="list-style-type: none"> • Dosage is individualized. Maximum dose: 100 mg.

			<p>Increase cautiously by 12.5 mg for doses >50 mg.</p> <p>Always check for particulate matter and discoloration before use.</p>
3.	Administration	How do I take it?	<p>Can be given intramuscularly or subcutaneously.</p> <p>Use a dry syringe and needle (at least 21 gauge).</p> <p>Wet syringe/needle may cause cloudiness.</p>
4.	Mechanism	Mechanism of Action	<p>Fluphenazine decanoate's effects are similar to fluphenazine hydrochloride, except for its longer duration of action due to esterification. It acts on the CNS and various organ systems, but its exact therapeutic mechanism is unknown. Compared to other phenothiazines, fluphenazine is more potent, less sedating, and has a weaker effect on CNS depressants and anesthetics. It is also less likely to cause hypotension than older phenothiazines.</p>
5.	Warning	Black Box Warning	<p>Increased Mortality in Elderly Patients with Dementia-Related Psychosis</p> <p>Fluphenazine Decanoate: Not approved for treating dementia-related psychosis.</p>
6.	Pregnancy	Use in Pregnancy	<p>The safety of this drug during pregnancy has not been established; potential risks should be weighed against the benefits when administered to pregnant patients.</p>
7.	Warnings	While using the medication	<p>Potential of the effects of alcohol may occur with the use of this drug.</p>
8.	Storage	What are the storage conditions?	<p>Store at 20° to 25°C (68° to 77°F). Protect from light (keep in outer carton).</p>
9.	Dispensing	How to Dispense?	<p>As prescribed by the Physician</p>
10.	Contraindication	What are the contraindications of (medication).	<ul style="list-style-type: none"> • Phenothiazines are contraindicated in patients with suspected or established subcortical brain damage. • Phenothiazine compounds should not be used in patients receiving large doses of hypnotics. • Fluphenazine Decanoate Injection is contraindicated in comatose or severely depressed states. • The presence of blood dyscrasia or liver damage precludes the use of fluphenazine decanoate. • Fluphenazine Decanoate Injection is not intended for use in children under 12 years of age. • Fluphenazine Decanoate Injection is contraindicated in patients who have shown hypersensitivity to fluphenazine; cross-sensitivity to phenothiazine derivatives may occur.

Pharmaceutical Particulars			
11.	Pharmaceutical Form	How is it supplied?	Fluphenazine Decanoate Injection, USP 25 mg/mL, is available in 5 mL multiple dose vials, packaged in individual carton. NDC: 72205-100-01.
12.	Ingredients	Active and Inactive Ingredients	Active: Fluphenazine Decanoate Inactive: Benzyl Alcohol, Sesame oil.
Allergens			
13.	Ingredients	Is it Vegetarian?	Yes
14.	Ingredients	Does it contain Gluten?	No
15.	Ingredients	Does it contain Dairy Products?	No
16.	Ingredients	Does it contain Casein	No
17.	Ingredients	Does it contain Whey?	No
18.	Ingredients	Does it contain corn?	No
19.	Ingredients	Does it contain rye?	No
20.	Ingredients	Does it contain sugar?	No
21.	Ingredients	Does it contain Oats?	No
22.	Ingredients	Does it contain wheat?	No
23.	Ingredients	Does it contain spelt?	No
24.	Ingredients	Does it contain barley?	No
25.	Ingredients	Does it contain rennet?	No
26.	Ingredients	Does it contain starch?	No
27.	Ingredients	Does it contain Iodine?	No
28.	Ingredients	Does it contain latex?	No
29.	Ingredients	Does it contain alcohol?	Yes; API contains solvents within the limits as per ICH
30.	Ingredients	Does it contain dyes?	No
31.	Ingredients	Does it contain flavor?	No
32.	Ingredients	Does it contain Lactose?	No
33.	Ingredients	Does it contain Nuts?	No
34.	Ingredients	Does it contain Preservatives?	No
35.	Ingredients	Does it contain Soy products?	No
36.	Ingredients	Does it contain peanut?	No
37.	Ingredients	Does it contain nickel?	No
38.	Ingredients	Does it contain Latex?	No; Free from latex
Miscellaneous			

39.	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.
40.	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
41.	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.
42.	Miscellaneous	How do I report an adverse drug effect or reaction to Novadoz medication?	To report suspected adverse reactions, contact Novadoz Pharmaceuticals LLC at 1-855-668-2369 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
43.	Miscellaneous	Why does my pharmacy that used to fill your generic formulation of a particular medicine, no longer fills my prescription with Novadoz formulation?	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.
44.	Miscellaneous	Manufacturer and Distributor	Manufactured by: MSN Laboratories Private Limited, Unit – II, Formulations Division, Nandigama