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| **FLUPHENAZINE DECANOATE INJECTION USP 125 mg5 mL (25 mg/mL) Multiple-Dose Vials** |
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| S.No. | **Category** | **Question** | **Answer** |
| **Clinical Particulars** |
|  | Use/Indication | What is the product indicated for? | 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).

***Fluphenazine Decanoate Injection has not been shown effective in the management of behavioral complications in patients with mental retardation.*** |
|  | Dosage | What is the recommended dosage? | 1. Initial Dose:* 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.

2. Maintenance Therapy:* Single injection may control symptoms for up to 4 weeks, potentially 6 weeks in some patients.

3. Initial Therapy for Naive Patients:* Start with a shorter-acting fluphenazine to assess response before switching to decanoate.

4. Conversion from Oral Fluphenazine:* 20 mg daily of Fluphenazine Hydrochloride ≈ 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.

5. Severely Agitated Patients:* Start with a rapid-acting phenothiazine, then follow with 25 mg (1 mL) of Fluphenazine Decanoate.

6. Dosage Adjustments:* Dosage is individualized. Maximum dose: 100 mg. Increase cautiously by 12.5 mg for doses >50 mg.

Always check for particulate matter and discoloration before use. |
|  | Administration | How do I take it? | Can be given intramuscularly or subcutaneously. ***Use a dry syringe and needle (at least 21 gauge).*** ***Wet syringe/needle may cause cloudiness.*** |
|  | Mechanism  | Mechanism of Action | 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. |
|  | Warning | Black Box Warning | Increased Mortality in Elderly Patients with Dementia-Related Psychosis***Fluphenazine Decanoate: Not approved for treating dementia-related psychosis.*** |
|  | Pregnancy | Use in Pregnancy | The safety of this drug during pregnancy has not been established; potential risks should be weighed against the benefits when administered to pregnant patients. |
|  | Warnings | While using the medication | Potentiation of the effects of alcohol may occur with the use of this drug. |
|  | Storage | What are the storage conditions? | Store at 20° to 25°C (68° to 77°F). Protectfrom light (keep in outer carton). |
|  | Dispensing | How to Dispense? | As prescribed by the Physician |
|  | Contraindication | What are the contraindications of (medication). | * Phenothiazines are contraindicated in patients with suspected or established subcorticalbrain damage.
* Phenothiazine compounds should not be used in patients receiving large doses ofhypnotics.
* Fluphenazine Decanoate Injection is contraindicated in comatose or severely depressedstates.
* The presence of blood dyscrasia or liver damage precludes the use of fluphenazinedecanoate.
* Fluphenazine Decanoate Injection is not intended for use in children under 12 years ofage.
* Fluphenazine Decanoate Injection is contraindicated in patients who have shownhypersensitivity to fluphenazine; cross-sensitivity to phenothiazine derivatives mayoccur.
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| **Pharmaceutical Particulars** |
|  | 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. |
|  | Ingredients | Active and Inactive Ingredients | **Active**: Fluphenazine Decanoate**Inactive**: Benzyl Alcohol, Sesame oil. |
| **Allergens** |
|  | Ingredients | Is it Vegetarian? | Yes |
|  | Ingredients | Does it contain Gluten? | No |
|  | Ingredients | Does it contain Dairy Products? | No |
|  | Ingredients | Does it contain Casein | No |
|  | Ingredients | Does it contain Whey? | No |
|  | Ingredients | Does it contain corn? | No |
|  | Ingredients | Does it contain rye? | No |
|  | Ingredients | Does it contain sugar? | No |
|  | Ingredients | Does it contain Oats? | No |
|  | Ingredients | Does it contain wheat? | No |
|  | Ingredients | Does it contain spelt? | No |
|  | Ingredients | Does it contain barley? | No |
|  | Ingredients | Does it contain rennet? | No |
|  | Ingredients | Does it contain starch? | No |
|  | Ingredients | Does it contain Iodine? | No |
|  | Ingredients | Does it contain latex? | No |
|  | Ingredients | Does it contain alcohol? | Yes; API contains solvents within the limits as per ICH  |
|  | Ingredients | Does it contain dyes? | No |
|  | Ingredients | Does it contain flavor? | No |
|  | Ingredients | Does it contain Lactose? | No |
|  | Ingredients | Does it contain Nuts? | No |
|  | Ingredients | Does it contain Preservatives?  | No |
|  | Ingredients | Does it contain Soy products? | No |
|  | Ingredients | Does it contain peanut? | No |
|  | Ingredients | Does it contain nickel? | No |
|  | Ingredients | Does it contain Latex? | No; Free from latex |
| **Miscellaneous** |
|  | 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. |
|  | Miscellaneous | May I know about return, refunds and reimbursement? | Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500 |
|  | 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.  |
|  | 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.  |
|  | 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. |
|  | Miscellaneous | Manufacturer and Distributor | Manufactured by:MSN Laboratories Private Limited,Unit – II, Formulations Division, Nandigama |