

Rx Fluphenazine Decanoate Injection I.P.

AMERICAN
FLUZICAN 25 Injection

Composition :

Each ml contains :	
Fluphenazine Decanoate I.P.	25 mg
Benzyl Alcohol I.P.	1.2% v/v
(As Preservative)	
Sesame Oil	q.s.

FOR IM USE Only

WHAT'S IN YOUR MEDICINE

Fluphenazine Decanoate Injection IP is a clear, light-yellow, sterile injection in clear glass ampoules.

Active ingredient: Fluphenazine decanoate.

Inactive ingredient: Sesame oil.

Type of medicine: Fluphenazine decanoate belongs to a group of medicines known as phenothiazine neuroleptics. It is used to improve the symptoms of major mental disorders.

USES

Fluphenazine Decanoate Injection IP is a long-acting preparation. It may be used when prolonged treatment is required to improve the symptoms of major mental disorders such as in schizophrenia or paranoia (paranoia means having a strong but abnormal belief such as false sense of persecution).

BEFORE YOU ARE GIVEN FLUPHENAZINE DECANOATE INJECTION

DO NOT USE Fluphenazine Decanoate injection if:

You are allergic to Fluphenazine Decanoate or any of the other ingredients.

You have severe heart disease or problems with the blood vessels supplying blood to the brain.

You have tumour of the adrenal gland (a condition called as 'phaeochromocytoma').

You are suffering from liver or kidney failure

You have severe depression

You have a blood disorder

Fluphenazine Decanoate Injection should not be given when the patient is in coma.

Do not have this medicine if any of above apply to you. If you are not sure, talk to your doctor or nurse before being given Fluphenazine Decanoate injection.

Take special care and tell your doctor if:

You have liver or kidney problems

You have an irregular heart beat or heart disease. If you or a member of your family has ever had heart disease, your doctor may carry out tests on your heart and blood before giving you this medicine.

You or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots.

You have abnormal functions of thyroid gland

You have lung infection

You are exposed to organophosphorus compounds

Even though some of above may be obvious, it is important that your doctor is aware if any of them apply to you.

Taking other medicines:

Do not take this medicine if you are taking:

Medicines used to induce the sleep or relieve the pain e.g. barbiturate, codeine

Medicines like quinidine, disopyramide, procainamide, amiodarone, sotalol used to control your heart beat

Medicines used to treat depression like lithium, tricyclic antidepressants (e.g. amitriptyline), tetracyclic anti-depressants (e.g. maprotiline),

phenothiazines, pimozide, MAO inhibitors and selective serotonin reuptake inhibitors (SSRIs) like fluoxetine.

This medicine can increase chance of side effect if you are taking:

Medicine used during surgery like general anaesthetics

Medicines used to prevent blood clotting like warfarin

Medicines used to treat irritable bowel syndrome, asthma or muscular spasms

Anticholinergic medicines (e.g. Atropine)

Medicines used for inflammation such as Corticosteroids (e.g. hydrocortisone or prednisolone).

Medicines used for fits such as phenytoin and carbamazepine

Pregnancy and breast-feeding

Tell your doctor before you are given this medicine if you are pregnant, think you may be pregnant or are planning to become pregnant or are breast-feeding unless your doctor decides that treatment is essential. This is because small amounts may pass into mothers' milk. Ask your doctor or nurse for advice before taking any medicine if you are pregnant or breastfeeding.

Driving and using machines

Fluphenazine Decanoate injection could interfere with your ability to drive or to use machines. Do not drive or operate machinery whilst you are taking this medicine. When your Fluphenazine Decanoate injection treatment has stopped, ask your doctor when it will be safe for you to drive or use machines.

HOW THIS MEDICINE IS ADMINISTERED

Fluphenazine Decanoate Injection IP is administered by injection deep into a muscle. At the start of treatment, your doctor may want to bring you into hospital to stabilise your treatment. Usually, it takes one to three days before your medicine starts to act, and two to four days for it to have a significant effect on your symptoms.

Dosage for adults

If you are receiving a long-acting injection form of fluphenazine for the first time, you may be given 12.5mg to start by deep injection into a muscle in your buttock. This dose should be halved (6.25mg) if you are over 60 years of age. After your first injection, your doctor will decide on what further doses you require and how often they should be given. Most patients can be successfully maintained on doses of between 12.5mg and 100mg given every two to five weeks. If you are resuming treatment with a long-acting injection form of fluphenazine, you may be given the same dose as the one you were receiving before your treatment was stopped. In this case, your doctor may want you to receive your injections more frequently in the early weeks of treatment until your symptoms are properly controlled. If you are elderly, your doctor may prescribe smaller maintenance doses to reduce the possibility of your medicine causing unwanted effects. Or as directed by the physician. This medicine is not recommended for use in children.

POSSIBLE SIDE EFFECTS

Like all medicines, Fluphenazine Decanoate injection can cause side effects, although not everybody gets them. All medicines can cause allergic reactions although serious allergic reactions are very rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash itching especially those covering your whole body should be reported to a doctor immediately.

If you are experiencing the following side effects while taking your medicine, you should stop taking your injection and tell your doctor straight away:

Rigid or stiff muscles, trembling or shaking, difficulty moving (acute dystonic reaction)

Yellowing of the skin or eyes (jaundice)

A sudden high temperature

High temperature, excessive sweating, stiff muscles, fast heartbeat, fast breathing and feeling confused, drowsy or agitated. These could be signs of a serious side effect called 'neuroleptic malignant syndrome'

In elderly people with dementia, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics.

Other possible side effects:

Feeling dizzy, light-headed or faint (due to low blood pressure), Swelling of the feet and legs (oedema), Feeling drowsy or tired

Difficulty in sleeping (insomnia), Feeling excited, agitated, Headache, stuffy nose, vomiting, Eye disorder (disturbances in vision)

Fluphenazine Decanoate injection can change the levels of liver enzymes or body fats such as cholesterol shown up on blood test

Talk to your doctor or nurse if any of the side effects gets serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet. As with other phenothiazine medicines, there have been very rare reports of sudden death with Fluphenazine Decanoate injection. These are possibly caused by heart problems.

STORING YOUR MEDICINE

Do not use this product after the expiry date printed on the ampoule label and carton. Store at room temperature not exceeding 30°C. Protect from light. Keep the container in the outer carton in order to protect from light. Do not refrigerate. If only part of the contents of an ampoule is used, discard the remaining solution. Keep the medicine out of reach of children.

PACK:

Ampoule of 1ml

Carton of 10 x 1 ml

Marketed by:



American Remedies Healthcare Pvt. Ltd.

(An ISO 9001-2015 Certified Company)

ICO: American Remedies LLC, DE, USA

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Manufactured by:

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