

Package leaflet: Information for the patient

Modecate Injection 25 mg/ml Solution for injection Modecate Concentrate 100 mg/ml Solution for injection Fluphenazine Decanoate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you..

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- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse. - This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

If you want to know more, or are not sure about anything, ask your doctor.

In this leaflet:

1. What Modecate is and what it is used for
2. What you need to know before you use Modecate
3. How to use Modecate
4. Possible side effects
5. How to store Modecate
6. Contents of the pack and other information

1. What Modecate is and what it is used for

This medicine is called Modecate and contains the active ingredient fluphenazine decanoate which belongs to a group of medicines called phenothiazines. These are classed as major tranquillisers and are used to treat nervous disorders.

Modecate is used to treat and control chronic schizophrenia and other mental illnesses.

Modecate has a long lasting effect and is particularly useful if you have difficulty remembering to take tablets regularly.

2. What you need to know before you use Modecate

Do not use Modecate:

- If you are **allergic** (hypersensitive) to fluphenazine decanoate or any of the other ingredients (see section 6)
- If you take a high dose of medicine to help you sleep
- If you suffer, or have ever suffered from any of the following:
 - Comatose states
 - Stroke or mini stroke (otherwise known as a transient ischaemic attack or TIA)
 - A tumour on the adrenal gland called Pheochromocytoma
 - Kidney or liver failure
 - Severe heart failure
 - Severe depression
 - Blood disorders

Modecate should not be given to premature babies or neonates (babies younger than 30 days old).

Warnings and precautions

Talk to your doctor before using Modecate:

- If you have any liver or kidney problems
- If you have had any serious disease affecting your lungs
- If you have ever suffered from a stroke
- If you have ever had an allergic reaction to similar medicines
- If you, or an immediate family member, have any heart problems including irregular heartbeat
- If 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.
- If you, or an immediate family member, suffers from an eye disease called glaucoma
- If you have diabetes, thyroid disease, enlarged prostate, Parkinson's disease, or myaesthesia gravis (a condition causing muscle weakness).
- If you have epilepsy
- If you have brain damage
- If you suddenly stopped drinking alcohol and are having signs of withdrawal. This may happen if you suddenly stop drinking large amounts for a long time, or stop after periods of very heavy drinking
- If you are going to be exposed to very hot weather
- If you are elderly (65 years of age or over) particularly if you are in poor health or being exposed to very cold weather
 - If you are exposed phosphorous insecticides
 - If you have any soreness in the mouth, gums or throat or any symptoms of upper respiratory infection occur and low red blood cells count
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If you are receiving this medication, a treatment card should be carried indicating the dosage received.

Other medicines and Modecate

Tell your doctor or pharmacist if you are taking, , or have recently taken, used or might take any of the following medicines:

- Any other medicines used to treat and control schizophrenia or any other mental illness, including Lithium
- Any sleeping tablets or strong painkillers
- Medicines to treat high blood pressure. These include diuretics such as bendroflumethiazide; ACE inhibitors such as captopril; beta blockers such as sotalol and other medicines including guanethidine or clonidine
- Medicines to treat heart failure or irregular heartbeat (e.g. quinidine or digoxin)
- Medicines to stop the blood from clotting (e.g. warfarin)
- Medicines to treat Parkinson's disease (e.g. L-Dopa)
- Medicines used to treat diabetes
- Medicines used to treat epilepsy
- Medicines used to treat depression. These include MAO inhibitors such as isocarboxazid and phenelzine; SSRIs such as citalopram, and TCA such as clomipramine hydrochloride
- Medicines used for HIV infection (protease inhibitors), such as amprenavir and indinavir
- Medicines to control your heartbeat (such as amiodarone, sotalol, procainamide, disopyramide or quinidine)
- Medicines used for life threatening allergic reactions or conditions such as adrenaline, dobutamine and dopamine

- Medicines which may cause vomiting or diarrhoea (e.g. antibiotics and laxatives)
- Any steroids
- Any muscle relaxants
- Water tablets (diuretics)
- Corticosteroids used for inflammation
- Ecstasy (MDMA)
- Anticholinergic medicines- includes some medicines used for irritable bowel syndrome, asthma or incontinence
- Cimetidine-for stomach ulcers or excess acid
- Medicines used to raise blood pressure (adrenergic vasoconstrictors) such as ephedrine and phenylephrine. Phenylephrine can be found as a decongestant in over-the-counter cold remedies.

If you are due to have any surgery, tell your doctor or surgeon that you are taking this medicine as it may affect general anaesthetics.

During the first months of treatments routine blood count and liver function tests are advisable.

Children

Modecate should not be given to children

Taking Modecate with food, drink and alcohol

Do not drink alcohol while you are having Modecate. This is because alcohol can increase the effects of Modecate and cause serious breathing problems.

Pregnancy and breast-feeding

Please tell your doctor if you are, or think you may be pregnant.

If you are pregnant, your doctor will only use this product if he considers that the potential benefit outweighs the risk. The lowest possible dose should be administered for the shortest duration.

The following symptoms may occur in new born babies, of mothers that may have used Modecate in the last trimester (last three months of pregnancy): shaking muscle stiffness and/or weakness, sleepiness, agitation, breathing problems and difficulty in feeding. If your baby develops any of these symptoms, you may need to contact your doctor.

You should not breast feed while you are being treated with Modecate. Do not restart breast feeding until your doctor tells you it is safe to do so.

Driving and using machinery

Modecate may cause blurred vision or difficulty in reading, especially during the first few weeks of treatment. You may also feel drowsy or less alert than normal. Therefore if this happens, do not drive or operate heavy machinery.

Important information about some of the ingredients of Modecate

Modecate Injection contains 15 mg of benzyl alcohol per ml. Benzyl alcohol must not be given to premature babies or neonates. It may cause toxic reactions and anaphylactoid reactions in infants and children up to 3 years old.

This product contains sesame oil which may rarely cause severe allergic reactions.

3. How Modecate is given

Your Modecate treatment will be given to you by a doctor or a nurse.

In adults, treatment is usually started with a dose of 12.5 mg, given by deep intramuscular injection, usually into the buttock.

Subsequent dosage is usually 25 mg every 2 to 4 weeks. This may be increased to 100 mg depending on your illness. Dosage should not exceed 100 mg. If doses greater than 50 mg is necessary, the next dose and succeeding dose should be increased cautiously in increments of 12.5 mg

Patients over 60 years of age are given a lower starting dose of 6.5 mg and usually a reduced maintenance dose.

If you miss a dose of Modecate

The dose of Modecate that you receive and the time between injections will be worked out by your doctor to provide you with the best treatment. It is important that you keep your appointments for injections. If you cannot keep an appointment, e.g. you are ill, contact your doctor or nurse as soon as possible so that other arrangements can be made.

4. Possible Side Effects

Like all medicines Modecate can cause side effects, although not everybody gets them.

This medicine may affect body temperature regulation, particularly in elderly patients. While you are receiving Modecate, take extra care not to become overheated during exercise or hot weather and avoid hot baths or saunas which may make you feel dizzy or faint. In addition, elderly patients, or those with an underactive thyroid, may also be at risk from hypothermia in cold weather. **Tell your doctor immediately** if you feel unusually hot or very cold.

Please tell you doctor immediately if you have:

- A sudden high temperature or an infection due to low numbers of white blood cells. These could be signs of a problem called "leucopenia"
- Bruising more than usual. This could be because of a blood disorder (thrombocytopenia)
- Blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately
- Joint aches and pains, swollen joints, increased sensitivity to sunlight, mouth ulcers, hair loss, anxiety, fever, night sweats, stomach pain, chest pain and shortness of breath. This could also be due to an immune condition called Systemic Lupus Erythematosus (SLE)
- Convulsions (body shaking rapidly and uncontrollably) or tremors, fast or irregular heartbeat, fever, loss of bladder control, severe muscle stiffness, jerky movements of the hands or the feet or unusual facial movements

Tell your doctor if you suffer from unusual tiredness, drowsiness or weakness, or have unusually pale skin or persistent infections, as it may be necessary for you to have blood tests.

You should also report back to your doctor as soon as possible if you have blurred vision or other visual disturbances, changes to your eye pigmentation, cataract, difficulty in speaking or swallowing, unusual movements of the tongue, fainting, muscle spasms or stiffness in the arms or legs.

Other side effects include dry mouth, nasal congestion, constipation, dizziness, difficulty in thinking or concentrating, yellowing of the skin (jaundice), increased level of cholesterol in the blood, low blood pressure, unusual antibodies, rash, changes in skin colour, swelling or pain in the breast, unusual secretion of milk, abnormal menstrual periods, decreased sexual ability, swelling of the feet and ankles, difficulty passing water (urine).

As with other phenothiazine medicines, there have been very rare reports of sudden death with Modecate. These are possibly caused by heart problems.

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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: + 353 1 6764971
Fax: + 353 1 6762517
Website: www.hpra.ie;
E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Modecate

This medicine will be stored in a pharmacy or by the doctor or nurse until it is administered to you.

Keep out of the reach and the sight of children.

Do not use Modecate after the expiry date which is shown on the carton and label after 'EXP'. The expiry date refers to the last day of the month. Do not store above 25°C. Do not refrigerate or freeze.

Keep vials or ampoules in the outer carton to protect from light. Refrigeration will cause precipitation of triglycerides from the sesame oil. If precipitation does occur, warming the product to 37°C will dissolve the precipitate without harming the active ingredient.

The in-use shelf life for the 10 ml multidose vial of Modecate Injection 25 mg/ml solution for injection is 28 days. The ampoule is for single use only. Once opened, use immediately. Any unused contents should be discarded.

6. Further Information

What Modecate contains

The active ingredient is: fluphenazine decanoate.

The other ingredients are: sesame oil and benzyl alcohol.

What Modecate looks like and contents of the pack

Modecate Injection 25 mg/ml solution for injection is available in multidose vials of 10ml, each of which contains 250 mg fluphenazine decanoate equivalent to 25 mg/ml.

Modecate Concentrate 100 mg/ml solution for injection is available in cartons of 10 x 0.5 ml ampoules or 5 x 1 ml ampoules. The 0.5 ml ampoule contains 50 mg fluphenazine decanoate and the 1ml ampoule contains 100 mg.

Marketing Authorisation Holder

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