

Modecate® 25mg/ml Injection

fluphenazine decanoate

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Is this leaflet hard to see or read?
Phone 0845 372 7101 for help

SANOFI

Read all of this leaflet carefully before you start using this medicine

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor, nurse or pharmacist
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist

In this leaflet:

1. What Modecate is and what it is used for
2. Before you are given Modecate
3. How Modecate is given
4. Possible side effects
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1. What Modecate is and what it is used for



The name of your medicine is Modecate 25mg/ml Injection (called Modecate throughout this leaflet). Modecate contains a medicine called fluphenazine decanoate. This belongs to a group of medicines called 'phenothiazines'. It works by blocking the effect of a chemical in the brain.

Modecate can be used for:

- Schizophrenia - this illness can make you feel, see or hear things which do not exist, have strange and frightening thoughts, change how you act and make you feel alone. Sometimes people with these symptoms may also feel tense, anxious or depressed
- Paranoid psychoses - this illness may make you feel very anxious or afraid for your own well-being.

2. Before you are given Modecate



Do not have this medicine and tell your doctor if:

- × You are allergic (hypersensitive) to:
 - fluphenazine decanoate
 - other phenothiazine medicines
 - the other ingredients of Modecate (listed in Section 6 below)

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

- × You have a tumour on the adrenal gland called a 'phaeochromocytoma'
- × You have ever had a stroke or mini stroke (otherwise known as a transient ischaemic attack or TIA)
- × You have severe heart problems
- × You have severe liver or kidney problems
- × You have severe depression
- × You have a blood disorder
- × You have been recently exposed to organophosphates

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

You should not be given Modecate if you are in a coma.



Take special care with Modecate. Check with your doctor or nurse before you have this medicine if:

- ▲ You have liver or kidney problems
 - ▲ You have an uneven heartbeat 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 problems with your thyroid gland
 - ▲ You have severe breathing problems
 - ▲ You have epilepsy
 - ▲ You have brain damage
 - ▲ You have Parkinson's disease
 - ▲ You have had problems with other medicines for psychotic diseases
 - ▲ You or members of your family have ever had glaucoma (painful eyes with blurred vision)
 - ▲ You have suddenly stopped drinking alcohol and are having signs of withdrawal. This may happen if you suddenly stop after drinking large amounts for a long time, or stop after a period of very heavy drinking
 - ▲ You have a form of muscle weakness called 'myasthenia gravis'
 - ▲ You have an enlarged prostate gland. This means you may have problems when passing water (urine)
 - ▲ You are going to be exposed to very hot weather
 - ▲ You are elderly (65 years of age or older) particularly if you are in poor health or during very cold weather
 - ▲ You are going to have an operation soon
- If you are not sure if any of the above apply to you, talk to your doctor or nurse before having Modecate.



Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Modecate can affect the way some other medicines work. Also some medicines can affect the way Modecate works.

In particular, do not have this medicine and tell your doctor if you are taking:

- Medicines to control your heartbeat (such as amiodarone, sotalol, procainamide, disopyramide or quinidine)
- Medicines used for depression
- Other medicines used to calm emotional and mental health problems such as chlorpromazine, lithium and pimozide
- Some medicines used for infections such as sparflaxacin and pentamidine
- Some medicines used for hay fever, rashes or other allergies called antihistamines (such as terfenadine)
- Water tablets (diuretics)
- Quinine - used for malaria

The following medicines can increase the chance of you getting side effects, when taken with Modecate:

- General anaesthetics - used during surgery
- Medicines to help you sleep (sedatives, barbiturates)
- Medicines for severe pain
- Medicines used to prevent blood clotting (anticoagulants), such as warfarin. Your doctor may change your dose and may monitor your treatment closely
- Digoxin - used for heart problems. Your doctor may change your dose and may monitor your treatment closely
- Anticholinergic medicines - includes some medicines used for irritable bowel syndrome, asthma or incontinence
- Corticosteroids used for inflammation such as hydrocortisone, betamethasone or prednisolone
- Medicines used for muscle spasms such as suxamethonium, pancuronium and dantrolene
- Medicines for high blood pressure
- Some medicine used for HIV infection (protease inhibitors) such as amprenavir and indinavir
- Gimetidine - for stomach ulcers or excess acid
- Cocaine or Ecstasy (MDMA)
- Phenylpropanolamine - used in colds and flu medicines

The following medicines can affect the way Modecate works or Modecate can affect the way some of these medicines work:

- Some medicines used for life threatening allergic reactions or conditions such as adrenaline, dobutamine and dopamine
- Medicines for Parkinson's disease (such as l-dopa, apomorphine, pergolide, lisuride, bromocriptine or cabergoline)
- Medicines used for fits (epilepsy) such as phenytoin and carbamazepine
- Medicines for diabetes
- Medicines used to raise blood pressure (adrenergic vasoconstrictors) such as ephedrine and phenylephrine
- Metrizamide - used to help with tests such as X-ray examinations
- Amfetamines - used for Attention Deficit Hyperactive Disorder (ADHD)

Positron Emission Tomography (PET) Studies

Having Modecate may affect the results PET studies carried out using labelled glucose. If you are going to have a PET study, it is important to tell your doctor you are having Modecate.

Having Modecate with food and drink

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

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant, or think you may be pregnant. Modecate may cause an incorrect false negative result on a pregnancy test. The following symptoms may occur in newborn babies, of mothers that have used Modecate in the last trimester (last three months of their 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 if you are taking Modecate. This is because small amounts may pass into mothers' milk. If you are breast-feeding or planning to

breast-feed, talk to your doctor or pharmacist before taking any medicine.

Ask your doctor or nurse for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

You may feel sleepy, tired, have blurred eyesight or your ability to think or respond may be lowered after having this medicine. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of Modecate

Modecate contains

- **Sesame oil.** This may cause severe allergic (hypersensitivity) reactions. The chances of this happening are rare. Tell a doctor or nurse straight away if you get a rash, swallowing or breathing problems and swelling of your lips, face, throat or tongue.
- **Benzyl alcohol.** Modecate Injection contains 15 mg/ml of benzyl alcohol. It must not be given to premature or newborn babies. Benzyl alcohol may cause toxic reactions and allergic reactions in infants and children up to 3 years old.

3. How Modecate is given

Modecate is normally given by a doctor or nurse. This is because it needs to be given as a deep injection into a muscle.

How much Modecate is given

If you are not sure why you are being given Modecate or have any questions about how much Modecate is being given to you, speak to your doctor or nurse.

The usual dose is:

- Adults** Modecate is usually given every 2 to 5 weeks.
- Your first dose will be 12.5mg
 - This may be increased up to 100mg depending on your illness
 - The usual dose is 12.5 to 100mg
- Elderly** Your doctor may start you on a lower dose of 6.25mg

Children

Modecate should not be given to children.

Tests

Before and during treatment your doctor may want to carry out some tests. These might include blood tests and an ECG to check your heart is working properly.

If you have more Modecate than you should

It is unlikely that your doctor or nurse will give you too much medicine. Your doctor and nurse will monitor your progress, and check the medicine you are given. Ask them if you are not sure why you are getting a dose of medicine.

Having too much Modecate may make you feel drowsy and you may become unconscious. You may also feel very cold, have a fast or irregular heartbeat or severe muscle spasms. If you start getting any of these symptoms tell your doctor or nurse straight away. If you are away from the hospital, return straight away and speak to your doctor or nurse or go to the casualty department.

If you miss a dose of Modecate

Your doctor or nurse will have instructions on when to give you this medicine. It is unlikely that you will not be given the medicine as it has been prescribed. However, if you do think you have missed a dose, tell your doctor or nurse.

If you stop having Modecate

Keep having Modecate until your doctor tells you to stop. If you stop having Modecate, your illness may come back and you may have other effects after stopping such as feeling or being sick, sweating and difficulty sleeping. You may also get tics (such as muscle spasms in your face, rolling eyes, jerking muscles) or feel restless.

4. Possible side effects

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



Tell a nurse or doctor straight away if you have;

- An allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- Yellowing of the skin or eyes (jaundice)
- A sudden high temperature or an infection due to low numbers of white blood cells. These could be signs of a problem called 'leucopenia'
- High temperature, sweating, stiff muscles, fast heartbeat, fast breathing and feel confused, drowsy or agitated. These could be signs of a serious side effect called 'neuroleptic malignant syndrome'
- Low temperature, unusually pale skin complexion, cold skin, uncontrollable shivering, slow breathing and slow heart beat. You may have low body temperature (hypothermia)
- Bruise more easily than usual. This could be because of a blood disorder (thrombocytopenia)
- Movements that you cannot control of the tongue, mouth, eyes, jaw, arms and legs
- Feel tired, weak, confused and have

muscles that ache, are stiff or do not work well. This may be due to low sodium levels in your blood or a condition called Syndrome of Inappropriate Anti-diuretic Hormone Secretion (SIADH)

- Joint aches and pains, swollen joints, increased sensitivity to sunlight, mouth ulcers, hair loss, anxiety, fevers, night sweats, stomach pain, chest pain and shortness of breath. This could also be due to changes to your immune system or an immune condition called Systemic Lupus Erythematosus (SLE)
- Fits
- An uneven or fast heartbeat
- 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.

Tell a nurse or doctor as soon as possible if you have any of the following side effects:

- Rigid or stiff muscles, trembling or shaking, difficulty moving
- Feeling dizzy, light-headed or faint (due to low blood pressure)
- Changes in skin or eye colour after having Modecate for a long time
- Swelling of the feet and legs (oedema)

Talk to your doctor or nurse if any of the following side effects gets serious or lasts longer than a few days:

- Feeling drowsy or tired
- Abnormal production of breast milk in men and women
- Breast enlargement in men
- Infrequent, light or loss of menstrual periods
- Sexual problems
- Difficulty sleeping (insomnia)
- Feeling excited, agitated
- Headache, stuffy nose, being sick (vomiting)
- Difficulty passing water (urine) or lack of control over passing water
- Blurred eyesight, dry mouth
- Less ability to perform mental tasks or having poor judgement
- Skin rashes
- Constipation

Tests

- Modecate can change the levels of liver enzymes or body fats such as cholesterol shown up on blood test
- Blood tests may show changes to your immune system

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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard 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 kept by your doctor or pharmacist in a safe place where children cannot see or reach it. Store below 25°C. Do not refrigerate or freeze. Keep the ampoules in the outer carton in order to protect from light.

Do not use Modecate after the expiry date, which is stated on the ampoule and the carton. The expiry date refers to the last day of the month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Modecate contains

- Each 1ml of the injection contains 25mg of the active substance, fluphenazine decanoate
- The other ingredients are sesame oil and benzyl alcohol

What Modecate looks like and contents of the pack

Modecate® 25 mg/ml Injection is a pale yellow clear liquid supplied in 0.5ml, 1ml and 2ml colourless glass ampoules with an OPC (one point cut) break system. Not all sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Sanofi, One Onslow Street, Guildford, Surrey, GU1 4YS, UK

Tel: 0845 372 7101

email: uk-medicalinformation@sanofi.com

Manufacturer

Bristol-Myers Squibb S.r.l., Contrada Fontana del Ceraso, 03012 Anagni (FR), Italy.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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