Before you are given it

Tell your doctor or pharmacist if you have allergies or reactions to:
- any other medicines, especially phenothiazine type medicines
- any other substances such as foods, preservatives or dyes

Tell your doctor if you have or have had any medical conditions especially the following:
- Brain damage, severe nervous system problems (severe CNS depression)
- Blood problems (e.g., leukopenia, thrombocytopenia, agranulocytosis)
- liver problems
- eye problems (e.g., glaucoma)
- heart problems (e.g., very high or very low blood pressure, mitral valve failure, irregular heartbeats)
- kidney problems
- cancer (e.g., pheochromocytoma)
- seizures
- chronic breathing problems
- bowel problems
- low blood calcium
- enlarged prostate
- drug or alcohol dependency
- Reyes syndrome
- nervous system problems (e.g., stroke, encephalitis, encephalopathy), dehydration
- diabetes
- thyroid disease
- Parkinson's disease or any other disorder that affects movement or causes muscle weakness

Tell your doctor if you are pregnant or intend to become pregnant. Like most phenothiazines, MODECATE is not recommended for use during pregnancy. If you need to be given MODECATE during your pregnancy, your doctor will discuss with you the benefits and risks of using it.

Tell your doctor if you are breast-feeding or plan to breast-feed. It is recommended that you do not breast-feed while taking MODECATE, as it may pass into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

Tell your doctor or dentist before having surgery (e.g., general anaesthetics) and mention that you are taking fluphenazine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Modecate Injection can alter the effect of certain medicines such as:
- sleeping tablets
- strong painkillers
- medicines to lower blood pressure, treat heart failure or irregular heartbeat
- beta-blockers (used to treat angina, migraine and glaucoma)
- medicines used to stop the blood from clotting
- medicines used to treat Parkinson's disease and epilepsy, as well as symptoms of other movement disorders
- medicines used to treat diabetes
- medicines used to treat depression
- medicines used to treat thyroid problems
- lithium
- steroids
- muscle relaxing agents
- antacids
- antihistamines
- general anaesthetics

Do not take other medicines used to treat and control schizophrenia and other mental illness, unless prescribed by your doctor.

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases your doctor may want to change the dosage or other precautions may be necessary. Your doctor will advise you.

Know the medicines you take. Keep a list of your medicines with you to show your doctor or pharmacist.

If you have not told your doctor about any of the above, tell them before you take MODECATE.

How MODECATE is given

How much is given

Your doctor will decide what dose you will receive and how frequently you should have an injection of MODECATE. Your dose depends on your condition and other factors such as your age or weight.

How it is given

MODECATE is given as a deep injection into a large muscle (intramuscular) by a doctor or nurse.

How often it is given

Usually MODECATE is given every four to six weeks. Your doctor will determine how often you need to be given MODECATE.

MODECATE helps to control your condition but does not cure it. Therefore you will need regular injections. Do not miss any injections, even if you feel better.

If you are not sure whether you should be having MODECATE, talk to your doctor or pharmacist.
If you are given too much (overdose)

As MODECATE is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any side effects, after being given MODECATE, tell your doctor immediately or go to Accident and Emergency at your nearest hospital. You may need urgent medical attention.

While you are being given MODECATE

Things you must do

Seek immediate medical attention if you develop the following:

- fever, muscle stiffness, severe confusion, increased sweating, fast or irregular heartbeat
- signs of infection (e.g., fever, persistent sore throat), easy bruising/bleeding
- severe stomach/abdominal pain, dark urine, yellowing of the eyes/skin
- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, asthma, wheezing, difficulty breathing or swallowing
- build up of fluid in the lungs, difficulty in breathing, wheezing or breathlessness.

Tell your doctor immediately if you notice any abnormal movements of the tongue, or other uncontrolled movements of the mouth, tongue, cheeks or jaw which may progress to the arms and legs.

This condition is more likely to occur during long-term treatment with MODECATE, especially in elderly women. It is very important that you see your doctor immediately as soon as any fine, uncontrolled movements of the tongue or twitches in the face start to occur.

Tell your doctor immediately if you notice any abnormal movement of the limbs, rotation of the eyes, body spasms of the back muscle, stiff limbs, drooling, mask-like stare, shuffling gait and mouth tremor.

These effects are usually reversible, and you should tell your doctor as soon as possible so that you can be treated quickly.

Tell any other doctors, dentists or pharmacists who are treating you that you are taking MODECATE.

If you are about to be started on any new medicine, tell your doctor, dentist and pharmacist that you are taking MODECATE.

If you plan to have any kind of surgery that needs medicine, tell your doctor, dentist and pharmacist who are treating you that you are taking MODECATE.

If you plan to have any blood/eye/skin tests from time to time. This helps to prevent unwanted side effects.

Things you must not do

Do not give MODECATE to anyone else, even if their symptoms seem similar, or they have the same condition as you.

Do not use MODECATE after the expiry date printed on the pack. If you take this medicine after this date has passed it may not work as well.

Do not use MODECATE if the packaging is damaged or shows signs of tampering; if this is the case, return it to your pharmacist.

Do not attempt to stop MODECATE without talking to your doctor, even if you feel better. If you stop MODECATE suddenly, your condition may worsen or your chance of getting an unwanted side effect may increase. To prevent this, your doctor may gradually reduce the amount of MODECATE you are given before stopping completely.

Do not take any medicines that cause drowsiness while you are using MODECATE, unless recommended by your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how MODECATE affects you.

MODECATE may cause some people to become drowsy or less alert than they are normally or cause light-headedness, dizziness or tiredness.

Be careful when drinking alcohol while taking MODECATE. Combining MODECATE and alcohol can make you more sleepy, dizzy or light-headed. Your doctor may suggest you avoid alcohol while you are being treated with MODECATE.

If outdoors, wear protective clothing and use at least a 15+ sunscreen. MODECATE may cause your skin to be much more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness or severe sunburn. If your skin does appear to be burning, tell your doctor. Do not use a solarium or tanning booth.

MODECATE may cause your eyes to be more sensitive to sunlight than they are normally. Exposure to sunlight may cause a skin rash, itching, redness or severe sunburn. If your skin does appear to be burning, tell your doctor. Do not use a solarium or tanning booth.

MODECATE may cause you to become drowsy or less alert than they are normally. Exposure to sunlight may cause a skin rash, itching, redness or severe sunburn. If your skin does appear to be burning, tell your doctor. Do not use a solarium or tanning booth.

MODECATE may cause you to become drowsy or less alert than they are normally. Exposure to sunlight may cause a skin rash, itching, redness or severe sunburn. If your skin does appear to be burning, tell your doctor. Do not use a solarium or tanning booth.

If outdoors, wear protective clothing and use at least a 15+ sunscreen. MODECATE may cause your skin to be much more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness or severe sunburn. If your skin does appear to be burning, tell your doctor. Do not use a solarium or tanning booth.

SIDE EFFECTS

The most frequent side effects are drowsiness, lethargy, dizziness, nausea, loss of appetite, sweating, dry mouth, stuffy nose, blurred vision, headache, or constipation. If any of these effects persist or worsen, notify your doctor or pharmacist promptly.

The following side effects are serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if any of these unlikely but serious side effects occur:

- feelings of restlessness
- mask-like facial expression
- greatly increased saliva
- tremors, unusual mental/mood changes (e.g., depression, worsening of psychosis), confusion
- unusual dreams
- frequent urination or difficulty urinating
- vision problems
- weight change
- swelling of the feet/ankles
- fainting
- skin discolouration
- butterfly-shaped facial rash
- joint/muscle pain
- seizures

Fluphenazine may rarely cause a condition known as tardive dyskinesia. In some cases, this condition may be permanent. Tell your doctor immediately if you develop any unusual/uncontrolled movements (especially of the face, mouth, tongue, arms, or legs).

In rare instances, this medication may increase your level of a certain hormone (prolactin).

For females, this rare increase in prolactin may result in unwanted breast milk, missing/stopped menstrual periods, or difficulty becoming pregnant. For males, it may result in decreased sexual ability, inability to produce sperm, or enlarged breasts.

If you develop any of these symptoms, tell your doctor immediately.

For males, in the very unlikely event you have a painful or prolonged erection lasting 4 or more hours, seek immediate medical attention, or permanent problems could occur.

This medication may rarely cause a serious condition called neuroleptic malignant syndrome (NMS).

Seek immediate medical attention if you develop the following: fever, muscle stiffness, severe confusion, increased sweating, fast or irregular heartbeat.

This drug may infrequently cause serious blood problems (e.g., agranulocytosis, leukaemia) or liver problems. Seek immediate medical attention if you notice any of the following rare but very serious side effects:
signs of infection (e.g., fever, persistent sore throat), easy bruising/bleeding, severe stomach/abdominal pain, dark urine, yellowing of the eyes/skin.

Tell your doctor immediately, or go to accident and emergency at your nearest hospital if you notice any of the following signs of a sudden life-threatening allergic reaction:

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, asthma, wheezing, difficulty breathing or swallowing
- build up of fluid in the lungs, difficulty in breathing, wheezing or breathlessness, which may be very severe and usually worsens on lying down.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

---

**After using MODECATE**

**Storage**

Keep your injections in a cool place, protected from direct sunlight, where the temperature stays below 25°C. Do NOT refrigerate or freeze your MODECATE injections. Keep your MODECATE injections in the pack until it is time to be given an injection. If you take the injections out of the pack they may not keep well.

Do not store MODECATE or any other medicine in the bathroom or near a sink. Do not leave it in a car or on windowsills. Heat and dampness can destroy some medicines. Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Alternatively MODECATE may be stored in the pharmacy, on the ward or in the clinic.

**Disposal**

If your doctor tells you to stop having MODECATE injections, or the medicine has passed its expiry date, your doctor, pharmacist or health care professional will dispose of any left over MODECATE.

---

**Product Description**

**What it looks like**

MODECATE Injection is supplied in ampoules containing an oily liquid.

**Ingredients**

Each ampoule contains: fluphenazine decanoate sesame seed oil, benzyl alcohol

**Presentation**

MODECATE is supplied in the following ampoule sizes in packs of five ampoules:

- 0.5 ampoule - AUST R 19263
- 1 mL ampoule - AUST R 47023
- 2 mL ampoule - AUST R 47024

**Sponsored by**

Bristol-Myers Squibb Australia Pty Ltd,
4 Nexus Court, Mulgrave,
Victoria 3170, Australia

Date of Preparation: December 2013

AU_CMI_Modecate_V7.0_Dec13.docx