

Package leaflet: information for the user

Psytixol 20 mg/ml, 100 mg/ml and 200 mg/ml injection

(flupentixol decanoate)

Psytixol 20 mg/ml, 100 mg/ml and 200 mg/ml injection are referred to as Psytixol throughout the leaflet.

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Psytixol is and what it is used for

Psytixol contains the active substance Flupentixol decanoate. Psytixol belongs to a group of medicines known as antipsychotics (also called neuroleptics).

These medicines act on nerve pathways in specific areas of the brain and help to correct certain chemical imbalances in the brain that are causing the symptoms of your illness.

Psytixol is used for the treatment of schizophrenia and other psychoses.

Your doctor, however, may prescribe Psytixol for another purpose. Ask your doctor if you have any questions about why Psytixol has been prescribed for you.

2. What you need to know before you are given Psytixol

You must not be given Psytixol if you

- are allergic to flupentixol or the oil it is dissolved in (listed in section 6)
- are feeling less alert than usual, or are drowsy or sleepy, or have serious problems with your blood circulation
- have taken an excess of alcohol, barbiturates or opiate medicines such as morphine
- are excited or agitated

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given Psylixol if you:

- are allergic to similar neuroleptic medicines
- suffer from kidney or liver disease
- have a heart condition, including an irregular heartbeat (such as a slower heart beat); have had a recent heart attack or have problems that cause ankle swelling or shortness of breath
- have risk factors for stroke (e.g. smoking, hypertension)
- suffer from Parkinson's disease
- suffer from epilepsy, or have been told that you are at risk of having fits (for example because of a brain injury or because of alcohol withdrawal)
- suffer from an over or under active thyroid
- have severe breathing problems (such as asthma or bronchitis)
- suffer from glaucoma (raised pressure in the eye)
- suffer from a condition causing severe muscular weakness (myasthenia gravis)
- have a rare type of cancer of the adrenal gland which sits near the kidney (phaeochromocytoma)
- have an enlarged prostate
- have too little potassium or magnesium in your blood or a family history of irregular heart beats
- or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
- suffer from diabetes
- use other antipsychotic medicines

Thoughts of suicide and worsening of your depression or anxiety disorder

Flupentixol is also available in tablet form and at lower doses can be used to treat depression. If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when you first start taking your medicine, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think

your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Other medicines and Psytixol

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

The following medicines should not be taken at the same time as flupentixol:

- **treatments for an irregular heartbeat** such as quinidine, disopyramide, amiodarone, sotalol, bretylium, dofetilide.
- **antibiotics** such as moxifloxacin, erythromycin
- **antimalarials** such as quinine and mefloquine
- **antihistamines** (for hay fever or allergies)
- **treatments for gastroesophageal reflux disease** such as cisapride
- **other medicines used to treat schizophrenia and other mental illness** such as lithium, chlorpromazine, haloperidol, pimozide, sertindole, thioridazine

Medicines may affect the actions of other medicines and this can sometimes cause serious adverse reactions.

Please tell your doctor, pharmacist or nurse if you are taking, any of the following medicines:

- **antidepressants** such as amitriptyline
- **sleeping tablets or sedatives** such as barbiturates (e.g. amobarbital)
- **piperazine (for treating worms)**
- **cough and cold remedies** including those bought over the counter
- medicines containing **adrenaline**, flupentixol can reduce the effect of adrenaline and similar drugs
- **corticosteroids** for inflammatory conditions such as arthritis e.g. prednisolone
- **treatment for Parkinson's disease** such as levodopa
- metoclopramide (**anti-sickness medicine**)
- **treatments for hypertension** (high blood pressure) such as guanethidine, hydralazine, methyldopa or doxazosin
- **digoxin** to control heart rhythm
- **treatments for epilepsy** such as phenytoin, carbamazepine
- **anticoagulants** such as warfarin, used to prevent blood clots
- **medicines for diabetes** such as insulin or metformin as the dose of your diabetic medicine may need to be adjusted
- **sibutramine** used to reduce appetite
- medicines containing **atropine** (often used for colic)
- medicines that cause a disturbed water or salt balance (too little potassium or magnesium in your blood) such as **diuretics** for water retention and hypertension

Tell your doctor, dentist, surgeon or anaesthetist before any operation as flupentixol can increase the effects of general anaesthetics, muscle relaxing drugs and drugs used to prevent blood clots.

Psytixol with alcohol

You **should not** drink alcohol while being treated with this medicine because it may increase the sedative effects of alcohol, making you drowsier.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Psytixol should not be given to pregnant or breast-feeding mothers unless the benefits to the mother outweigh the risks to the baby.

Tell your doctor if you are pregnant or planning to become pregnant. Psytixol **should not** be given to you in the first or last three months of pregnancy as it can affect the growth of your unborn baby and may also affect your labour.

The following symptoms may occur in newborn babies of mothers that have used Psytixol 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.

While you are being given Psytixol, **do not** breast-feed your baby, as small amounts of flupentixol can pass into breast milk.

Driving and using machines

Do not drive or operate machinery during the early stages of treatment or if you drink alcohol as Psytixol may reduce your alertness. Do not drive if you have blurred vision.

Talk to your doctor before you drive or operate machinery.

3. How Psytixol is given

Your doctor will usually give you this injection deep into the muscle of your buttock or thigh.

Your doctor will decide on the correct amount of medicine to give, and how often to give it. The medicine is slowly released from the injection site so that a fairly constant amount of medicine gets into your blood during the period between each dose.

Adults

The usual dose lies between 50 mg every 4 weeks to 300 mg every 2 weeks but some patients require 400 mg every week. The maximum single dose at any one time is 400 mg. If you need more than 2 ml of medicine it will probably be divided between 2 injection sites.

If you have not received an injection like Psytixol before, a small dose of 20 mg is usually given one week before your normal dose to test how well you tolerate the medicine.

If you have been treated with flupentixol tablets and you are being transferred to Psytixol injection you may be asked to continue taking the tablets for several days after the first injection.

Your doctor may decide to adjust the amount given, or the interval between injections, from time to time.

Patients with liver problems:

If you have liver problems, the level of flupentixol in your blood may be checked.

Elderly patients (above 65 years)

In older or frail patients, the starting dose may be reduced to a quarter or half the normal starting dose.

Use in children

Psytixol is not recommended for children.

Duration of treatment

It may take between four and six months before you feel better. Your doctor will decide the duration of treatment.

If you feel that the effect of Psytixol injection is too strong or weak, talk to your doctor, pharmacist or nurse.

It is important that you continue to receive your medicine at regular intervals even if you are feeling completely well because the underlying illness may persist for a long time. If you stop your treatment too soon, your symptoms may return.

If you get more Psytixol than you should

Your medicine will be given by your doctor or nurse.

In the unlikely event that you receive too much Psytixol, you may experience some symptoms of overdose such as:

- Drowsiness
- Unconsciousness
- Muscle movements or stiffness
- Fits
- Low blood pressure, weak pulse, fast heart rate, pale skin, restlessness
- High or low body temperature
- Changes in heart beat including irregular heart beat or slow heart rate

You will receive treatment for any of these symptoms from your doctor or nurse.

If you stop your treatment with Psytixol

Even if you feel better after your treatment has started, you should see your doctor at the time they ask for further treatment. If you stop your treatment too soon your illness may return over the course of several weeks or months. Your doctor will decide when it is possible to stop your treatment and will gradually reduce the amount you receive to avoid any unpleasant

symptoms that might occur if it is stopped abruptly (e.g. unusual movements, feeling or being sick, difficulty sleeping).

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Older patients tend to be more likely to suffer from some of these effects than younger patients and this may mean your treatment is supervised more closely.

Serious side effects

Stop using Psytilol and seek medical advice immediately if you have any of the following:

- **allergic reactions:**
 - Difficulty in breathing
 - Swelling of the face, lips, tongue or throat which causes difficulty in swallowing or breathing
 - Severe itching of the skin (with raised lumps)

- **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.

If any of the following happen, tell your doctor **immediately** or go to your nearest hospital emergency department:

- High fever, unusual stiffness of the muscles and changes in consciousness, especially if occurring with sweating and fast heart rate. These symptoms may be signs of a rare but serious condition called neuroleptic malignant syndrome that has been reported with the use of Psytilol and similar medicines
- Unusual movements of the mouth and tongue as these may be early signs of a condition known as tardive dyskinesia
- Unusual muscle movements (such as circular movements of the eyes), stiffness, tremor and restlessness (for example difficulty in sitting or standing still) as these may be signs of a so-called "extra-pyramidal" reaction
- In rare cases irregular heart beats (arrhythmias) may have resulted in sudden death
- Any yellowing of the skin and the white in the eyes (jaundice); your liver may be affected

Other side effects

Side effects are most pronounced in the beginning of the treatment and most of them usually wear off during continued treatment.

Very common: may affect 1 in 10

- Sleepiness, sedation
- Restlessness or difficulty in standing still
- Reduced or slow body movements
- Uncontrollable muscle spasms affecting the eyes, head, neck and body, uncontrollable twitching, jerking or writhing movements
- Dry mouth

Common: may affect between 1 in 10 to 1 in 100 people

- An increase in appetite, increase in weight
- Depression
- Feeling nervous, agitated
- Decreased sexual drive
- Difficulty in sleeping
- Unusually overactive
- Tremor
- Dizziness
- Headache
- Lack of concentration
- Blurred eyesight
- Feeling tired, unusual weakness
- Fast heartbeat
- Shortness of breath
- Increase in the amount of saliva produced
- Constipation, being sick (vomiting), indigestion, diarrhoea
- Increased sweating, itching
- Muscle pain
- Passing urine when you do not mean to, passing urine more often than usual or unable to pass urine

Uncommon: may affect between 1 in 1000 to 1 in 100 people

- A decrease in appetite
- Disorder of the central nervous system, seen usually in the elderly, in which there is muscle weakness, trembling, sweating and slowing of movements (parkinsonism), speech disorder, fits
- Loss of sex drive, difficulty in getting and keeping an erection and difficulty in ejaculation
- A fall in blood pressure, which may make you feel dizzy and unwell, especially when you stand quickly
- Hot flush
- Stomach pain, feeling sick (nausea), wind
- Abnormal liver enzyme tests (seen in a blood test)
- Skin rashes or increased sensitivity to sunlight, redness, pain or painful lumps at the site of injection
- Muscle stiffness

- confusion

Rare: may affect between 1 in 1000 to 1 in 100 people

- Blood disorders such as lack of white blood cells, which may be characterised by fever or chills, sore throat, ulcerated mouth or throat, or decrease in the number of blood platelets which is characterised by unusual bleeding or unexplained bruising
- High prolactin levels in the blood
- Raised blood levels of glucose, loss of control of blood sugar levels
- Enlargement of the breasts in men and production of milk in both men and women
- Irregular or complete disappearance of periods
- Changes in the electrical tracing of the heart (ECG), irregular or abnormal heart rhythm and heart block have been reported for this type of medicine

Not known: can not be estimated from the available data

- Higher (hyperthermia) or lower (hypothermia) body temperature than normal
- Fluid retention (oedema)
- In elderly patients with dementia, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics
- Thoughts of harming or killing themselves (Suicidal ideation, suicidal behavior)
- Blood clots in your veins (Venous Thromboembolism (VTE))
- Withdrawal symptoms in the newborn baby (Drug withdrawal syndrome neonatal)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 Psytixol

Keep this medicine out of the sight and reach of children.

Your doctor will not use Psytixol after the expiry date, which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Your doctor will store this medicine below 25°C and in the original package.

Medicines should not be disposed of via wastewater or household waste. Your doctor will dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Psytixol contains

The active substance is flupentixol decanoate.

The other ingredient is medium chain triglycerides.

What Psytixol looks like and contents of the pack

Your medicine is in the form of an oily solution for deep intramuscular injection.

Psytixol is supplied in amber glass ampoules and is available in the following strengths and pack sizes:

- Psytixol 20 mg/ml injection is supplied in packs of 1, 5 or 10 ampoules. Each ampoule contains 1 or 2 ml of solution.
- Psytixol 100 mg/ml injection is supplied in packs of 1, 5 or 10 ampoules. Each ampoule contains 0.5 or 1 ml of solution.
- Psytixol 200 mg/ml injection supplied in packs of 5 or 10 ampoules where each ampoule contains 1 ml of solution.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

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