Depixol® 20 mg/ml solution for injection

2972
15.12.20[4]

(flupentixol decanoate)

PATIENT INFORMATION 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
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

This medicine is available using the above name but will be referred to as Depixol Injection throughout the leaflet.

What is in this leaflet:
1. What Depixol Injection is and what it is used for
2. What you need to know before Depixol Injection is given
3. How Depixol Injection is given
4. Possible side effects
5. How to store Depixol Injection
6. Contents of the pack and other information

1. WHAT DEPIXOL INJECTION IS AND WHAT IT IS USED FOR

The name of your medicine is Depixol 20 mg/ml solution for injection (called Depixol Injection in this leaflet).

Depixol Injection contains the active substance flupentixol decanoate.
Depixol Injection 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.

Depixol Injection is used for the treatment of schizophrenia and other psychoses.

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

2. WHAT YOU NEED TO KNOW BEFORE DEPIXOL INJECTION IS GIVEN

Depixol Injection is not given if you
- are allergic (hypersensitive) to flupentixol, other thioxanthene drugs or antipsychotic drugs or any of the other ingredients of this medicine (listed in section 6)
- are feeling less alert than usual or are drowsy or sleepy, or have serious problems with your blood circulation
- are excited or agitated

Warnings and precautions
Talk to your doctor, pharmacist or nurse before Depixol Injection is given if you:
- have a heart condition, including an irregular heart beat (such as a slower heart beat); have had a recent heart attack or have problems that cause ankle swelling or shortness of breath
- have severe breathing problems (such as asthma or bronchitis)
- have liver, kidney or thyroid problems
- 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 Parkinson's disease, or myasthenia gravis (a condition causing severe muscular weakness)
- have an enlarged prostate or suffer from a condition known as phaeochromocytoma (a rare type of cancer of a gland near the kidney)
- suffer from glaucoma (raised pressure within the eye)
- have risk factors for stroke (e.g. smoking, hypertension)
- have too little potassium or magnesium in your blood or a family history of irregular heart beats
- use other antipsychotic medicines
- suffer from diabetes
- or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
- are treated for cancer

Children and adolescents
Depixol Injection is not recommended in these patients.

Thoughts of suicide and worsening of your depression or anxiety disorder
If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, 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 Depixol Injection
Tell your doctor or pharmacist 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 Depixol Injection:
- Medicines that change the heartbeat (quinidine, amiodarone, sotalol, dofetilide, erythromycin, moxifloxacin, cisapride, lithium)
- Other antipsychotic medicines

Tell your doctor or pharmacist if you are taking any of the following medicines:
- Tricyclic anti-depressants
- Barbiturates or other medicines that make you feel drowsy
- Anticoagulant drugs used to prevent blood clots (e.g. warfarin)
- Anticholinergic drugs (contained in some cold, allergy or travel sickness remedies as well as other medicines)
- Metoclopramide (used to treat nausea and other stomach conditions)
- Piperazine (used to treat worm infections)
- Levodopa or other medicines used to treat Parkinson's disease
- Sibutramine (used to reduce appetite)
- Digoxin (to control heart rhythm)
- Corticosteroids (e.g. prednisolone)
- Medicines used to lower the blood pressure such as hydralazine, alpha blockers (e.g. doxazosin) betablockers, methyldopa, clonidine or guanethidine
- Medicines that cause a disturbed water or salt balance (too little potassium or magnesium in your blood)
- Medicines known to increase the concentration of flupentixol in your blood
- Medicines used to treat epilepsy
- Medicines used to treat diabetes

Depixol Injection can reduce the effect of adrenaline (epinephrine) and similar drugs.

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

Depixol Injection with alcohol
Depixol Injection may increase the sedative effects of alcohol making you drowsier. It is recommended not to drink alcohol during treatment with Depixol Injection.

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

Pregnancy
If you are pregnant or think you might be pregnant, tell your doctor. Depixol Injection should not be used during pregnancy unless clearly necessary.

The following symptoms may occur in newborn babies, of mothers that have used Depixol Injection 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.

Breast-feeding
If you are breast-feeding, ask your doctor for advice. Depixol Injection should not be used when breast-feeding, as small amounts of the medicine can pass into the breast milk.

Fertility
Flupentixol may decrease your sexual activity and fertility. These are not lasting effects. Please talk to your doctor about any problems.

Driving and using machines
There is a risk of feeling drowsy and dizzy when being treated with Depixol Injection, especially at the start of your treatment. If this happens do not drive or use any tools or machines until you know you are not affected in this way.

Do not drive if you have blurred vision.

3. HOW DEPIXOL INJECTION IS GIVEN

A small amount of Depixol Injection is drawn up into a syringe and then injected 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 haven't received an injection like Depixol Injection 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 Depixol tablets and you are being transferred to Depixol 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.

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

Older patients (above 65 years)
Starting doses for older or frail patients are usually reduced to a quarter or a half of the dosage range.

The following information is intended for healthcare professionals only:

Administration information for the healthcare professional

Depixol® 20 mg/ml solution for injection

Consult the Summary of Product Characteristics for full information on this product

Depixol 20 mg/ml solution for injection should be administered by deep intramuscular injection into the upper outer buttock or lateral thigh.

Note: As with all oil-based injections it is important to ensure, by aspiration before injection, that inadvertent intravascular entry does not occur.

The maximum single dose at any one time is 400 mg.
For example, 800 mg every 2 weeks should not be given.

Injection volumes greater than 2 ml should be distributed between two injection sites.

This product may be mixed in the same syringe with other products in the Depixol Injection range.

It should not be mixed with any other injection fluids.

Use in children
Depixol Injection 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 Depixol Injection is too strong or weak, talk to your doctor.

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 Depixol Injection than you should
Your medicine will be given by your doctor or nurse.

In the unlikely event that you receive too much Depixol Injection you may experience some symptoms.

Symptoms of overdose may include:
- 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.

4. POSSIBLE SIDE EFFECTS
Like all medicines, Depixol Injection 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 taking Depixol and seek medical advice immediately if you have any of the following allergic reactions:
Not known: frequency cannot be estimated from the available data
- 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 you get any of the following symptoms you should **contact your doctor immediately** as your dose may need to be reduced or stopped:
Very rare: may affect up to 1 in 10,000 people
- 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 Depixol Injection and similar medicines
- Unusual movements of the mouth and tongue as these may 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

Rare: may affect up to 1 in 1,000 people
- 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)

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 more than 1 in 10 people
- Drowsiness
- Dry mouth
- Muscle spasm
- Rigidity of the whole body

Common: may affect up to 1 in 10 people
- Changes in appetite or weight
- Insomnia
- Depression
- Nervousness or agitation
- Dizziness
- Headaches
- Reduction in your sex drive
- Poor concentration
- Blurred or abnormal vision
- Throbbing or fast heartbeats
- Shortness of breath
- Increase of saliva
- Vomiting
- Indigestion
- Diarrhoea
- Increased sweating or greasy skin
- Itching
- Muscle pain
- Tremor
- Abnormal urination (such as decrease in frequency or amount)
- General weakness or pain, tiredness or feeling unwell

Uncommon: may affect up to 1 in 100 people
- Confusion
- Loss of co-ordination or altered muscle movements (including unusual movements of the mouth, tongue and eyeballs)
- Speech problems
- Fits
- Low blood pressure
- Hot flushes
- Stomach pain
- Feeling sick
- Flatulence (wind) and constipation
- Abnormal liver function tests
- Rashes or skin reactions (including sensitivity to sunlight)
- Stiff and floppy muscle
- Problems with ejaculation or erections in male
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- Reduction in blood platelets (which increases the risk of bleeding or bruising) and other blood cell changes
- Raised blood levels of glucose or the hormone prolactin.
- Loss of control of blood sugar levels
- Breast enlargement in male
- Unexpected excretion of breast milk
- Women may experience an absence of menstrual periods

As with other medicines that work in a way similar to flupentixol decanoate (the active ingredient of Depixol Injection), rare cases of the following side effects have been reported:
- Slow heartbeat and abnormal ECG heart tracing.
- Life threatening irregular heart beats.

In older 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 or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE DEPIXOL INJECTION
Usually your doctor or nurse will store the medicine for you. If you keep it at home:
- Keep this medicine out of the sight and reach of children
- Do not use this medicine after the expiry date that is printed on the label. The expiry date refers to the last day of that month
- Keep the ampoules in the original package in order to protect from light.
- If your medicines show any signs of deterioration or discolouration, you should seek the advice of your pharmacist who will tell you what to do.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION
What Depixol Injection contains
The active substance is flupentixol decanoate.
Each ml of solution contains 20 mg flupenthixol decanoate.

The other ingredients are medium chain triglycerides.

What Depixol Injection looks like and contents of the pack
Depixol Injection is a clear, colourless or pale-yellow liquid, practically free from particles.

Depixol Injection is available in: Glass ampoules containing 1 ml (20 mg) in cartons of 10 ampoules.

Manufacturer and Product Licence Holder
Manufactured by H. Lundbeck A/S, Ottiliavej 9, 2500 Valby, Denmark.
Procured from within the EU by Product Licence holder:
Star Pharmaceuticals Ltd. 5 Sandridge Close, Harrow, Middlesex HA1 1XD.
Repackaged by Servipharm Ltd.

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Depixol is a trademark of H. Lundbeck A/S.

Blind or partially sighted?
Is this leaflet hard to see or read?
Call 020 8423 2111 to obtain the leaflet in a format suitable for you.

Flupentixol decanoate 20 mg/ml solution for injection

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- 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.
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This medicine is available using the above name but will be referred to as Flupentixol Injection throughout the leaflet.

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1. WHAT FLUPENTIXOL INJECTION IS AND WHAT IT IS USED FOR

The name of your medicine is Flupentixol decanoate 20 mg/ml solution for injection (called Flupentixol Injection in this leaflet).

Flupentixol Injection contains the active substance flupentixol decanoate. Flupentixol Injection 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.

Flupentixol Injection is used for the treatment of schizophrenia and other psychoses.

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

2. WHAT YOU NEED TO KNOW BEFORE FLUPENTIXOL INJECTION IS GIVEN

Flupentixol Injection is not given if you
- are allergic (hypersensitive) to flupentixol, other thioxanthene drugs or antipsychotic drugs or any of the other ingredients of this medicine (listed in section 6)
- are feeling less alert than usual or are drowsy or sleepy, or have serious problems with your blood circulation
- are excited or agitated

Warnings and precautions
Talk to your doctor, pharmacist or nurse before Flupentixol Injection is given if you:
- have a heart condition, including an irregular heart beat (such as a slower heart beat); have had a recent heart attack or have problems that cause ankle swelling or shortness of breath
- have severe breathing problems (such as asthma or bronchitis)
- have liver, kidney or thyroid problems
- 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 Parkinson's disease, or myasthenia gravis (a condition causing severe muscular weakness)
- have an enlarged prostate or suffer from a condition known as phaeochromocytoma (a rare type of cancer of a gland near the kidney)
- suffer from glaucoma (raised pressure within the eye)
- have risk factors for stroke (e.g. smoking, hypertension)
- have too little potassium or magnesium in your blood or a family history of irregular heart beats
- use other antipsychotic medicines
- suffer from diabetes
- or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
- are treated for cancer

Children and adolescents
Flupentixol Injection is not recommended in these patients.

Thoughts of suicide and worsening of your depression or anxiety disorder
If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, 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 Flupentixol Injection
Tell your doctor or pharmacist 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 Injection:
- Medicines that change the heartbeat (quinidine, amiodarone, sotalol, dofetilide, erythromycin, moxifloxacin, cisapride, lithium)
- Other antipsychotic medicines

Tell your doctor or pharmacist if you are taking any of the following medicines:
- Tricyclic anti-depressants
- Barbiturates or other medicines that make you feel drowsy
- Anticoagulant drugs used to prevent blood clots (e.g. warfarin)
- Anticholinergic drugs (contained in some cold, allergy or travel sickness remedies as well as other medicines)
- Metoclopramide (used to treat nausea and other stomach conditions)
- Piperazine (used to treat worm infections)
- Levodopa or other medicines used to treat Parkinson's disease
- Sibutramine (used to reduce appetite)
- Digoxin (to control heart rhythm)
- Corticosteroids (e.g. prednisolone)
- Medicines used to lower the blood pressure such as hydralazine, alpha blockers (e.g. doxazosin) betablockers, methyldopa, clonidine or guanethidine
- Medicines that cause a disturbed water or salt balance (too little potassium or magnesium in your blood)
- Medicines known to increase the concentration of flupentixol in your blood
- Medicines used to treat epilepsy
- Medicines used to treat diabetes

Flupentixol Injection can reduce the effect of adrenaline (epinephrine) and similar drugs.

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

Flupentixol Injection with alcohol
Flupentixol Injection may increase the sedative effects of alcohol making you drowsier. It is recommended not to drink alcohol during treatment with Flupentixol Injection.

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

Pregnancy
If you are pregnant or think you might be pregnant, tell your doctor. Flupentixol Injection should not be used during pregnancy unless clearly necessary.

The following symptoms may occur in newborn babies, of mothers that have used Flupentixol Injection 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.

Breast-feeding
If you are breast-feeding, ask your doctor for advice. Flupentixol Injection should not be used when breast-feeding, as small amounts of the medicine can pass into the breast milk.

Fertility
Flupentixol may decrease your sexual activity and fertility. These are not lasting effects. Please talk to your doctor about any problems.

Driving and using machines
There is a risk of feeling drowsy and dizzy when being treated with Flupentixol Injection, especially at the start of your treatment. If this happens do not drive or use any tools or machines until you know you are not affected in this way.

Do not drive if you have blurred vision.

3. HOW FLUPENTIXOL INJECTION IS GIVEN

A small amount of Flupentixol Injection is drawn up into a syringe and then injected 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 haven't received an injection like Flupentixol Injection 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 Flupentixol 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.

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

Older patients (above 65 years)
Starting doses for older or frail patients are usually reduced to a quarter or a half of the dosage range.

The following information is intended for healthcare professionals only:

Administration information for the healthcare professional

Flupentixol Decanoate 20 mg/ml solution for injection

Consult the Summary of Product Characteristics for full information on this product

Flupentixol Decanoate 20 mg/ml solution for injection should be administered by deep intramuscular injection into the upper outer buttock or lateral thigh.

Note: As with all oil-based injections it is important to ensure, by aspiration before injection, that inadvertent intravascular entry does not occur.

The maximum single dose at any one time is 400 mg.
For example, 800 mg every 2 weeks should not be given.

Injection volumes greater than 2 ml should be distributed between two injection sites.

This product may be mixed in the same syringe with other products in the Depixol Injection range.

It should not be mixed with any other injection fluids.

Use in children
Flupentixol Injection 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 Flupentixol Injection is too strong or weak, talk to your doctor.

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 Flupentixol Injection than you should
Your medicine will be given by your doctor or nurse.

In the unlikely event that you receive too much Flupentixol Injection you may experience some symptoms.

Symptoms of overdose may include:
- 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.

4. POSSIBLE SIDE EFFECTS
Like all medicines, Flupentixol Injection 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 taking Flupentixol and seek medical advice immediately if you have any of the following allergic reactions:
Not known: frequency cannot be estimated from the available data
- 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 you get any of the following symptoms you should **contact your doctor immediately** as your dose may need to be reduced or stopped:
Very rare: may affect up to 1 in 10,000 people
- 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 Flupentixol Injection and similar medicines
- Unusual movements of the mouth and tongue as these may 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

Rare: may affect up to 1 in 1,000 people
- 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)

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 more than 1 in 10 people
- Drowsiness
- Dry mouth
- Muscle spasm
- Rigidity of the whole body

Common: may affect up to 1 in 10 people
- Changes in appetite or weight
- Insomnia
- Depression
- Nervousness or agitation
- Dizziness
- Headaches
- Reduction in your sex drive
- Poor concentration
- Blurred or abnormal vision
- Throbbing or fast heartbeats
- Shortness of breath
- Increase of saliva
- Vomiting
- Indigestion
- Diarrhoea
- Increased sweating or greasy skin
- Itching
- Muscle pain
- Tremor
- Abnormal urination (such as decrease in frequency or amount)
- General weakness or pain, tiredness or feeling unwell

Uncommon: may affect up to 1 in 100 people
- Confusion
- Loss of co-ordination or altered muscle movements (including unusual movements of the mouth, tongue and eyeballs)
- Speech problems
- Fits
- Low blood pressure
- Hot flushes
- Stomach pain
- Feeling sick
- Flatulence (wind) and constipation
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- Raised blood levels of glucose or the hormone prolactin.
- Loss of control of blood sugar levels
- Breast enlargement in male
- Unexpected excretion of breast milk
- Women may experience an absence of menstrual periods

As with other medicines that work in a way similar to flupentixol decanoate (the active ingredient of Flupentixol Injection), rare cases of the following side effects have been reported:
- Slow heartbeat and abnormal ECG heart tracing.
- Life threatening irregular heart beats.

In older 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 or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE FLUPENTIXOL INJECTION
Usually your doctor or nurse will store the medicine for you. If you keep it at home:
- Keep this medicine out of the sight and reach of children
- Do not use this medicine after the expiry date that is printed on the label. The expiry date refers to the last day of that month
- Keep the ampoules in the original package in order to protect from light.
- If your medicines show any signs of deterioration or discolouration, you should seek the advice of your pharmacist who will tell you what to do.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION
What Flupentixol Injection contains
The active substance is flupentixol decanoate.
Each ml of solution contains 20 mg flupenthixol decanoate.

The other ingredients are medium chain triglycerides.

What Flupentixol Injection looks like and contents of the pack
Flupentixol Injection is a clear, colourless or pale-yellow liquid, practically free from particles.

Flupentixol Injection is available in: Glass ampoules containing 1 ml (20 mg) in cartons of 10 ampoules.

Manufacturer and Product Licence Holder
Manufactured by H. Lundbeck A/S, Ottiliavej 9, 2500 Valby, Denmark.
Procured from within the EU by Product Licence holder:
Star Pharmaceuticals Ltd. 5 Sandridge Close, Harrow, Middlesex HA1 1XD.
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