Package Leaflet: Information for the user

Depixol Conc. 100 mg/ml Solution for Injection

(cis(Z)-flupentixol decanoate)

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.

What is in this leaflet:

1. What Depixol Conc. Injection is and what it is used for

Depixol Conc. Injection contains the active substance flupentixol.

Depixol Conc. Injection belongs to a group of medicines known as antipsychotics.

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.

This medicine is used for the treatment of schizophrenia and other related psychoses.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

2. What you need to know before you use Depixol Conc. Injection

Do not use Depixol Conc. Injection if you:

- are allergic to flupentixol or any of the other ingredients of this medicine (listed in Section 6). Consult your doctor if you think you might be
- have a reduced level of alertness due to any cause (this includes reduced alertness after the consumption of alcohol or drugs such as opiates (e.g. morphine) or barbiturates)
- are an older person who suffers from confusion
- are receiving emergency treatment to support your blood circulation
- are a child
- are unconscious (in a coma)

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Depixol Conc. Injection if you:

- have a liver problem
- have a history of fits or convulsions or have any condition that might make you prone to fits e.g. head injury, alcohol withdrawal
- have Parkinson's disease
- have a respiratory disease (e.g. asthma or COPD (chronic obstructive pulmonary disease))
- are an older person (you may be at risk of low body temperature, sedation, low blood pressure or confusion)
- have dementia
- have diabetes (you may need an adjustment of your diabetes therapy)
- have a history of alcohol or drug abuse
- have a brain injury or disease
- have a mental retardation
- have risk factors for stroke (e.g. smoking, hypertension)
- are born with or have had an episode of abnormal heart rhythm (seen at ECG; an examination to evaluate how the heart is functioning) e.g. significantly lowered or irregular heart beat or any other heart condition (e.g. a heart attack).
- or anyone in your family has a heart condition
- are taking medicines that change the heartbeat or if you have hypokalaemia or hypomagnesaemia (too little potassium or magnesium in your blood)
- suffer from an under or over active thyroid, myasthenia gravis (a condition causing severe muscular weakness) or an enlarged prostate
- are about to undergo any procedure which will require a general anaesthetic (if this is for dentistry, tell your dentist)
- use other antipsychotic medicine

- are more excited or overactive than normal, since this medicine may increase these feelings
- 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 on long-term therapy (particularly with high dosage). Your doctor will review your treatment to decide whether the current dose can be lowered.
- are being treated for cancer.

Children and adolescents
Depixol Conc. Injection is not recommended in this patient group.

Other medicines and Depixol

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

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

- Tricyclic antidepressant medicines (e.g. amitriptyline, imipramine)
- Guanethidine, hydrazaline and similar medicines (used to lower the blood pressure)
- Other medicines that make you drowsy such as barbiturates
- Medicines used to treat epilepsy (e.g. phenytoin, sodium valproate, gabapentin, carbamazepine, lamotrigine)
- Levodopa and similar medicines (used to treat Parkinson's disease)
- Metoclopramide (used in the treatment of gastro-intestinal disorders)
- Piperazine (used in the treatment of roundworm and threadworm infections)
- Digoxin (used in the treatment of heart conditions)
- Corticosteroids (used to treat a range of conditions, including inflammatory diseases)
- Warfarin, ticlopidine, dipyramidole and similar medicines called anticoagulants (used to thin the blood)
- Medicines known as non steroidal anti-inflammatory drugs (NSAIDs e.g. ibuprofen, diclofenac, mefenamic acid) and aspirin which are used to relieve pain and to thin the blood)
- Medicines such as diuretics (water tablets) that cause a disturbed water or salt balance (too little potassium or magnesium in your blood)
- Medicines known as phenothiazines used to treat mental illness (e.g. chlorpromazine, fluphenazine).
- Medicines known as neuromuscular blocking agents (e.g. suxamethonium) as concomitant treatment with this medicine may prolong the effect of neuromuscular blocking agents
- Adrenergic medicines (e.g. atenolol) as concomitant treatment with this medicine may reduce their effect

The following medicines should not be taken with this medicine:

- Medicines for heart rhythm problems such as medicines used to treat irregular heartbeats (e.g. quinidine, amiodarone, sotalol, dofetilide), certain antibiotics (e.g. erythromycin, gatifloxacin, moxifloxacin), certain antihistamines (e.g. astemizole, terfenadine) and other medicines such as cisapride and lithium
- Other antipsychotic medicines (e.g. thioridazine)

Depixol Conc. Injection with alcohol

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

Pregnancy, breast-feeding and fertility

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

Pregnancy

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

The following symptoms may occur in newborn babies of mothers that have used this medicine 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. You should not this medicine when breast-feeding, as small amounts of the medicine can pass into the breast milk.

Fertility

Animal studies have shown that this medicine affects fertility. Please ask your doctor for advice.

Driving and using machines

There is a risk of feeling drowsy and dizzy when using this medicine. If this happens do not drive or use any tools or machines until these effects wear off.

3. How to use Depixol Conc. Injection

A small volume of Depixol Conc. 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 volume of medicine to give, and how often to give it. The medicine is slowly released from the injection during the period in between injections.

The recommended dose is:

Adults

The dose is adjusted according to the severity of symptoms and is usually between 0.5 ml every 4 weeks and 3 ml every two weeks. In early treatment, doses up to 4 ml per week may be given.

If you need more than 2 ml of medicine it will probably be divided between two injection sites.

If you have been receiving oral flupentixol medication (tablets) and you are being transferred to the intramuscular form of flupentixol you may be asked to continue taking 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.

Older people (above 65 years)
Older people are usually treated with doses in the lower end of the dosage range.

Patients with special risks
Patients with liver complaints normally receive doses in the lower end of the dosage range.

Use in children and adolescents
This medicine is not recommended for children and adolescents.

If you have the impression that the effect this medicine is too strong or too weak, talk to your doctor, pharmacist or nurse.

Duration of treatment
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.

Your doctor decides the duration of treatment.

If you get more Depixol Conc. Injection than you should

Your medicine will be given by your doctor/nurse.
In the unlikely event that you receive too much of this medicine you may experience some symptoms.

Symptoms of overdose may include:

- Drowsiness
- Unconsciousness
- Muscle movements or stiffness
- Convulsions
- Low blood pressure, weak pulse, fast heart rate, pallor, restlessness
- High or low body temperature
- Changes in heart beat including irregular heart beat or slow heart rate has been seen when this medicine has been given in overdose together with medicines known to affect the heart.

Symptomatic and supportive treatment will be initiated by your doctor/nurse.

4. Possible side effects

Like all medicines, Depixol Conc. Injection can cause side effects, although not everybody gets them.

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

If you experience any of the following symptoms contact your doctor or go to the hospital right away:

Common (may affect up to 1 in 10 people):

- Racing heart, a sensation of a rapid, forceful, or irregular beating of the heart.

Uncommon (may affect up to 1 in 100 people):

- Unusual movements of the mouth and tongue; this may be an early sign of a condition known as tardive dyskinesia

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

- Low blood platelet count. A common symptom is bruising of the skin. Low white blood cell count. Symptoms could be increased frequency of infections. Severe reduction in the number of white blood cells which makes infections more likely.

- Hypersensitivity, acute systemic and severe allergic reaction. Most severe allergic reactions involve the skin with development of hives, generalized redness and swelling of face, eyelids, lips, tongue, throat, hands, and feet. Other symptoms could be difficulty breathing, wheezing, chest tightness, rapid heart beat, dizziness and loss of consciousness. The symptoms of severe allergic reactions can vary. In some people, the reaction begins very slowly, but in most the symptoms appear rapidly and abruptly

Very rare (may affect up to 1 in 10,000 people):

- High fever, unusual stiffness of the muscles and altered mental status, especially if occurring with sweating and fast heart rate; these symptoms may be signs of a rare condition called neuroleptic malignant syndrome which has been reported with the use of different antipsychotics.

- Yellowing of the skin and the white in the eyes, this may mean that your liver is affected and a sign of a condition known as jaundice.

- 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

The following side effects have also been reported:

Very common (may affect more than 1 in 10 people)

- Sleepiness, inability to sit still or remain motionless, involuntary movements, slow or diminished movements
- Dry mouth

Common (may affect up to 1 in10 people):

- Tremor, twisting or repetitive movements or abnormal postures due to sustained muscle contractions, dizziness, headache
- Difficulties focusing on objects near to the eye, vision abnormalities

- Difficulty breathing or painful breathing
- Increased saliva secretion, constipation, vomiting, digestive problems or discomfort centred in the upper abdomen, diarrhoea
- Urination disorder, lack of ability to urinate
- Increased sweating, itching
- Muscle pain
- Increased appetite, increased weight
- Fatigue, weakness
- Insomnia, depression, nervousness, agitation, decreased sexual drive

Uncommon (may affect up to 1 in 100 people):

- Jerky movements, tremor and difficulty in controlling movements, speech disorder, convulsion
- Circular movement of the eye
- Abdominal pain, nausea, flatulence
- Rash, skin reaction due to sensitivity to light, eczema or inflammation of the skin
- Muscle rigidity
- Decreased appetite
- Low blood pressure, hot flush
- Red or sore skin where the Depixol Conc. Injection was given
- Abnormal liver function tests
- Sexual disturbance (delayed ejaculation, problems with erection)
- State of confusion

Rare (may affect up to 1 in 10 people):

- High blood sugar, abnormal glucose tolerance. Often there are no symptoms. Hyperglycaemia over long time could show as fatigue, weight loss, excessive thirst and urination.

- Increased level of prolactin in the blood. Symptoms of hyperprolactinaemia could be excessive milk production, lack of menstrual periods and development of breasts in men.

As with other medicines that work in a way similar to Depixol rare cases of the following side effects have been reported:

- Slow heart beat and change in the ECG
- Irregular heart beat
- Torsade de Pointes (a special kind of irregular heart beat)

In rare cases irregular heart beats may have resulted in sudden death.

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.

If you stop taking this medicine too quickly, you may experience discontinuation symptoms. The most common discontinuation symptoms are nausea, vomiting, loss of appetite, diarrhoea, runny nose, sweating, pains in the muscles, feelings like pins and needles,

insomnia, restlessness, anxiety or agitation. You may also experience dizziness, alternate feelings of warmth and coldness and shakiness. The symptoms usually begin within 1 to 4 days of stopping Depixol and go away within 7 to 14 days. If you get severe discontinuation symptoms, contact your doctor for advice.

Reporting of side effects

Ireland

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 HPRA Pharmacovigilance Website: www.hpra.ie.~~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.

Malta

ADR Reporting
The Medicines Authority
Post-Licensing Directorate
Sir temi Zammit Buildings
Malta Life Sciences Park
San Gwann SGN 300
Website: www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt~~.....~~

5. HOW TO STORE DEPIXOL CONC. INJECTION

Usually your doctor or nurse will store your 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 which is stated on the label or carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions.

Keep Depixol Conc. Injection ampoules in the box, so they are protected from light.

Once opened, use immediately and discard any unused solution.

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 protect the environment.

6. Contents of the pack and other information

What Depixol Conc. Injection contains

The active substance is cis(Z)-flupentixol decanoate.
Each millilitre (ml) of Depixol Conc. Injection contains 100 mg cis(Z)-flupentixol decanoate.

The other ingredient is thin vegetable oil (triglycerides, medium chain).

What Depixol Conc. Injection looks like and contents of the pack

Depixol Conc Injection is presented as 100 mg/ml solution for injection.

Description of Depixol Conc. Injection
Depixol Conc. Injection is a clear yellowish to yellow oil, practically free from particles.

This medicine is available in glass ampoules containing 1 ml (100 mg) in boxes of 10 ampoules.

Marketing Authorisation Holder and Manufacturer

Depixol Conc. Injection is made by:
H. Lundbeck A/S
Ottiliavej 9
2500 Valby
Denmark

Marketing Authorisation Holder

Lundbeck (Ireland) Limited
4045 Kingwood Road
Citywest Business Park
Citywest
Co.Dublin
Ireland

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