XP1-048-22-COMB-13401

Package leaflet: Information for the user

Deanxit® film-coated tablets

flupentixol 0.5 mg (as dihydrochloride) + melitracen 10 mg (as hydrochloride)

Read all of this leaflet carefully before you start taking 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Deanxit is and what it is used for

Deanxit contains the active substances flupentixol and melitracen. Deanxit belongs to a group of medicines that work by relieving the symptoms of depressed mood.
In combination the active substances render a preparation with antidepressant, anxiolytic and activating properties.

Deanxit is used to treat anxiety and depression in patients with or without psychosomatic symptoms.

2. What you need to know before you take Deanxit

Do not take Deanxit
- if you are allergic to flupentixol, melitracen or any of the other ingredients of this medicine (listed in section 6).if you have diminished consciousness
- if you have a blood disease
- if you have a rare abnormality of the adrenal glands (phaeochromocytoma)
- if you recently have had a heart attack (myocardial infarction)
- if you have disturbances in heart rhythm which are seen on an electrocardiogram (ECG)
- at the same time as taking medication known as monoamine oxidase inhibitors (MAOIs)

MAOIs include medicines such as phenelzine, iproniazid, isocarboxazid, nialamide, tranylcypromine and moclobemide all of which are also used for the treatment of depression and selegiline, which is used in the treatment of Parkinson's disease. Even if you have finished taking one of the following MAOIs: phenelzine, iproniazid, isocarboxazid, nialamide or tranylcypromine for depression or selegiline for Parkinson's disease you will need to wait 2 weeks before you start taking Deanxit.
One day must elapse after you have finished taking moclobemide.

Deanxit tablets are not suitable for patients with severe depression, for example patients required to stay in hospital or patients requiring electroconvulsive therapy (ECT), nor are they suited for excited or overactive patients.

Warnings and precautions
Talk to your doctor or pharmacist before taking Deanxit if you
- have an organic brain syndrome (which may be a resulting condition after poisoning with alcohol or organic solvents)
- have a history of convulsions
- have difficulty urinating
- have an overactive thyroid gland (hyperthyroidism)
- have a liver or heart disease
- are more excited or overactive than normal, since this medicine may increase these feelings
- have hypokalemia or hypomagnesia (to little potassium or magnesium in your blood or genetic predisposition for any of these)
- have a history of cardiovascular disorders
- have diabetes (you may need an adjustment of your antidiabetic therapy)
- have glaucoma (increased eye pressure)
- are getting surgery, it is advisable to stop administering the product several days before the operation
- are taking medication known as selective serotonin reuptake inhibitor (SSRI)
- if you, or someone else in your family, have a history of blood clots, as medicines like these have been associated with formation of blood clots

Children and adolescents
Deanxit is not recommended for use in children and adolescents.

Older people
In older people with dementia, a slight increase in the number of deaths has been reported in patients taking antipsycotics compared with patients not taking these medicines.

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.

Episodes of mania
Some patients with manic-depressive illness may enter into a manic phase. This is characterized by profuse and rapidly changing ideas, exaggerated gaiety and excessive physical activity. In such cases, it is important to contact your doctor who probably will change your medication.

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

Tell your doctor if you are taking any of the following medicines:
- Adrenaline, ephedrine, isoprenaline, noradrenaline, phenylephrine and phenylpropanolamine (which is in some cold remedies)
- Guanethidine and similar medicines (used to lower the blood pressure)
- Tricyclic antidepressants
- Medicines that change the heartbeat (quinidine, amiodarone, sotalol, dofetilide, thioridazine, erythromycin, terfenadine, astemizole, gatifloxacin, moxifloxacin, cisapride, lithium)
- Medicines that cause a disturbed water or salt balance (too little potassium or magnesium in your blood)
- Medicines known to increase the concentration of Deanxit in your blood
- Medicines which cause drowsiness (alcohol, barbiturates and other drugs with sedative effect)
- Lithium (used in the prophylaxis and treatment of manic-depressive disorder)
- Levodopa (used to treat Parkinson's disease)

Deanxit with food, drink and alcohol
Deanxit may increase the sedative effects of alcohol making you drowsier. It is recommended not to drink alcohol during treatment with Deanxit.

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.

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

The following symptoms may occur in newborn babies, of mothers that have used Deanxit 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 use Deanxit when breast-feeding, as small amounts of the medicine can pass into the breast milk.

Fertility
Animal studies have shown that Deanxit affects the fertility. Please ask your doctor for advice.

Driving and using machines
Deanxit generally does not cause drowsiness; however, if you feel dizzy or sleepy when you start to take these tablets, do not drive or work any tools or machinery until these effects wear off.

Deanxit contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Deanxit

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults
Usually 2 tablets per day: 1 in the morning and 1 at noon.
Your doctor may increase the dose to 2 tablets in the morning and 1 at noon.
The maximum dose is 4 tablets per day.
Maintenance dose: Usually 1 tablet in the morning.

Older people (above 65 years)
1 tablet in the morning.

Your doctor may increase the dose to 1 tablet in the morning and 1 at noon.
Maintenance dose: Usually 1 tablet in the morning.
Deanxit can be taken with or without food.
Swallow the tablets with a drink of water. Do not chew them.

Duration of treatment
Patients often respond to Deanxit treatment quite quickly, but if you have been taking the maximum dose for a week or so and still do not feel better, your doctor may decide to stop the treatment.

Your doctor decides the duration of treatment. Continue to take the tablets for as long as your doctor recommends. Never change the dose of the medicine without talking to your doctor first.

If you take more Deanxit than you should
If you think that you or anyone else may have taken too many Deanxit tablets contact your doctor or nearest hospital casualty department immediately. Do this even if there are no signs of discomfort or poisoning. Take the Deanxit container with you if you go to a doctor or hospital.

Symptoms of overdose may include sleepiness, irritability, restlessness, hallucinations, dilated pupils, fast heart rate, difficulty urinating, mucosal dryness, constipation, convulsions, fever, unconsciousness, coma, difficulty breathing (blue discoloration of the skin), irregular heartbeat, heart problems which can cause shortness of breath or ankle swelling, low blood pressure, metabolic acidosis, hypokalaemia (low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm).

If you forget to take Deanxit
If you forget to take a dose, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Deanxit
Do not stop taking Deanxit even if you begin to feel better, unless you are told to do so by your doctor.

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.

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

Very rare (may affect up to 1 in 10,000 people):
- Unusual movements of the mouth and tongue; this may be an early sign of a condition known as tardive dyskinesia.

- High fever, unusual stiffness of the muscles and disorder of your consciousness, 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.

- Signs of infection such as sudden unexplainable fever, sore throat and mouth ulcers; this may be signs of a strongly reduced number of white blood cells and a condition known as agranulocytosis.

Not known (frequency cannot be estimated from the available data):
- Suicidal thoughts or behaviour, see also section “Warnings and precautions”.

- 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 are most pronounced in the beginning of the treatment and most of them usually wear off during continued treatment:

Common (may affect up to 1 in 10 people):
- Sleeplessness (insomnia), restlessness
- Sleepiness, tremor, dizziness
- Difficulties focusing on objects near to the eye (accommodation disorder)
- Dry mouth
- Constipation
- Fatigue
- Abnormal electrocardiogram (ECG) heart tracing

Uncommon (may affect up to 1 in 100 people):
- Nightmare, anxiety, state of confusion
- Fast heart rate (tachycardia), irregular heart beat (arrhythmia)
- Abnormal liver function tests
- Rash, hair loss (alopecia)
- Muscle pain (myalgia)
- Feeling of weakness

Rare (may affect up to 1 in 1,000 people):
- Nausea
- Digestive problems or discomfort centered in the upper abdomen (dyspepsia)

Very rare (may affect up to 1 in 10,000 people):
- Low blood platelet count (thrombocytopenia), reduced white blood cell count (leukopenia)
- Jerky movements (dyskinesia), tremor, stiffness and shuffling (parkinsonism)
- Liver disease

Not known (frequency cannot be estimated from the available data):
- Drug withdrawal syndrome in newborn babies, see also section “Pregnancy, breast-feeding and fertility”

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. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Deanxit

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. The expiry date refers to the last day of that month.

Store below 25°C.
Store in the original package in order to protect from light.

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 Deanxit contains
The active substances are flupentixol and melitracen. Each Deanxit film-coated tablet contains flupentixol dihydrochloride corresponding to 0.5 mg flupentixol and melitracen hydrochloride corresponding to 10 mg melitracen.

The other ingredients are betadex, lactose monohydrate, maize starch, hydroxypropylcellulose, microcrystalline cellulose, croscarmellose sodium, talc, hydrogenated vegetable oil, magnesium stearate.

Coating: polyvinyl alcohol part. hydrolyzed, macrogol 3350, talc, Macrogol 6000.
Colours: titanium dioxide E 171, erythrosine E 127, indigotine E 132.

What Deanxit looks like and contents of the pack
Deanxit film-coated tablets are round, biconvex, cyclamen.

Deanxit tablets are available in blister packs or plastic containers in the following pack sizes:

30, 50, and 100 in blister pack
100 in plastic container

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
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This leaflet was last revised in September 2015