



Deanxit® coated tablets

flupentixol (as dihydrochloride) + melitracen (as hydrochloride)

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Deanxit is and what it is used for
2. Before you take Deanxit
3. How to take Deanxit
4. Possible side effects
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1. WHAT DEANXIT IS AND WHAT IT IS USED FOR

How does Deanxit work

Deanxit belongs to a group of medicines, which work by relieving the symptoms of depressed mood.

In combination the active substances render a preparation with antidepressant, anxiolytic and activating properties.

What is Deanxit used for

Deanxit is used to treat anxiety and depression in patients who may, or may not also be showing signs of psychosomatic affections.

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

2. BEFORE YOU TAKE DEANXIT

Do not take Deanxit

- If you are hypersensitive (allergic) to flupentixol, melitracen or any of the other ingredients of Deanxit. Consult your doctor if you think you might be.
- 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 which are also used for the treatment of depression.

Even if you have finished taking one of the following MAOIs: phenelzine, iproniazid, isocarboxazid, nialamide or tranylcypromine you will need to wait 2 weeks before you start taking your Deanxit tablets.

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.

Take special care with Deanxit

Please tell your doctor if you have any medical problems, especially if you have

- A liver problem
- A history of convulsions or fits
- Diabetes (you may need an adjustment of your antidiabetic therapy)

- An organic brain syndrome (which may be a resulting condition after poisoning with alcohol or organic solvents)

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Children and adolescents

Deanxit is not recommended for use in children and adolescents due to lack of data on efficacy and safety. Treatment with Deanxit is associated with a risk of cardiovascular adverse events in all age groups.

Suicide risk associated with psychiatric disorders

Suicidal thoughts are common in psychiatric disorders especially in patients suffering from depression. They will often persist until the antidepressant effect of the medication becomes apparent. Let your family and caregivers know how you feel and tell your doctor if your depressive symptoms become worse.

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.

Taking other medicines

Some drugs may affect the action of another and this can sometimes cause serious adverse reactions.

Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription. This also includes other medication for depression (see *Do not take Deanxit above*).

When using Deanxit with the following medicines, caution should be exercised:

- Tricyclic antidepressant medications
- Lithium (used in the prophylaxis and treatment of manic-depressive disorder)
- Ephedrine, isoprenaline, noradrenaline, phenylephrine and phenylpropanolamine (which is in some cold remedies)
- Anticholinergic drugs (e.g. atropine, hyoscyamine)
- Drugs which lower blood pressure
- Drugs which cause drowsiness
- Drugs for epilepsy
- Levodopa (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)

If you are going to have an operation and receive general or local anaesthetics you should tell that you are taking Deanxit.

Likewise, you should tell your dentist that you take Deanxit if you are to receive a local anaesthetic.

Taking Deanxit with food and drink

Deanxit can be taken with or without food.

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

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

The general condition of your newborn baby might be affected by the use of this group of medicines.

Mothers should not breast-feed their babies while taking this medicine.

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.

Important information about some of the ingredients of Deanxit tablets

This product contains lactose and sucrose. 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

How much to take

Always take Deanxit exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure or need further information.

Adults

Usually 2 tablets daily: 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.

Elderly patients (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.

Children and adolescents (≤18 years)

Deanxit should not be given to children or adolescents. For further information please see section 2.

If you have the impression that the effect of Deanxit is too strong or too weak, talk to your doctor or pharmacist.

How and when to take Deanxit

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 tablets.

The duration of treatment is decided by your doctor. Continue to take the tablets for as long as your doctor recommends. Do not stop taking them even if you begin to feel better, unless you are told to do so by your doctor.

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:

- Drowsiness or excitement
- Unconsciousness
- Difficulty in breathing, blue discoloration of the skin
- Dilated pupils
- Convulsions
- Fast heart beats
- Low blood pressure, weak pulse, pallor
- Fever

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.

4. POSSIBLE SIDE EFFECTS

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

These are few and mild and usually wear off during continued treatment.

If side effects are troublesome or last for more than a few days tell your doctor

Dry mouth increases the risk of caries. Therefore you should brush your teeth more often than usual.

Common side effects (in more than 1 and less than 10 out of 100 patients) may include:

- Dizziness, tremor.
- Blurred vision (difficulty in reading small print).
- Difficulty in falling asleep, restlessness, agitation.
- Dry mouth, constipation.
- Fatigue.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE DEANXIT

Always keep medicines out of reach and sight of children.

Store Deanxit below 25°C.

There is an expiry date on the label. Do not use the medicine after this date.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Deanxit contains

The active substances are flupentixol (as dihydrochloride) and melitracen (as hydrochloride).
Each Deanxit sugar coated tablet contains flupentixol dihydrochloride corresponding to 0.5 mg flupentixol and melitracen hydrochloride corresponding to 10 mg melitracen.

The other ingredients are lactose monohydrate, potato starch, gelatin, talc, magnesium stearate.
Coating: Gelatin, sucrose, sucrose powder; Wax polish - a mixture of Beeswax, white and carnauba wax.
Deanxit colour (erythrosine, E 127 and indigotine, E 132).

What Deanxit looks like and contents of the pack

Description of Deanxit tablets

Deanxit tablets are round, biconvex, cyclamen, sugar-coated.

Deanxit tablets are available in blister packs, polypropylene containers or glass bottle in the following pack sizes:
20,30,50, 60 and 100 in blister pack
50 and 100 in polypropylene container
500 in glass bottle

Not all pack sizes may be marketed.

Manufacturer

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