DEFAXINE®
75 mg Capsules

Dear patient,
Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about DEFAXINE
Each DEFAXINE extended release capsule for oral administration contains venlafaxine HCl equivalent to venlafaxine 75 mg with the following excipients: colloidal anhydrous silica, povidone, ethylcellulose, titanium dioxide, purified talc.
The mechanism of the antidepressant action of venlafaxine is associated with its potentiation of neurotransmitter activity in the CNS. Venlafaxine and its active metabolite, O-desmethylvenlafaxine (ODV), are potent inhibitors of neuronal serotonin and norepinephrine reuptake and weak inhibitors of dopamine reuptake.
DEFAXINE is indicated in the treatment of the following conditions:
- Major Depressive Disorder
- Generalized Anxiety Disorder
- Social Anxiety Disorder (Social Phobia)
- Panic Disorder with or without agoraphobia

The way to take DEFAXINE
Take DEFAXINE as directed by your physician. Do not discontinue the treatment without consulting your doctor.
Dosage and duration of treatment are individualized and adjusted according to the condition under treatment and the response obtained.
The usual recommended doses for adults are:

Indication	**Dosage**
Major depressive disorder	The recommended starting dose is 75 mg/day, administered in a single dose. A gradual dose increase may be considered if insufficient clinical improvement is observed, up to a maximum of 225 mg daily. Dose increases should be made at intervals of not less than 4 days.
Generalized anxiety disorder	
Social anxiety disorder (social phobia)	The recommended starting dose is 75 mg/day, administered in a single dose.
Panic disorder	The recommended starting dose is 37.5 mg/day, administered in a single dose for 7 days, followed by doses of 75 mg/day and subsequent weekly dose increases of 75 mg/day to a maximum dose of 225 mg/day.

DEFAXINE should be administered with food either in the morning or in the evening at approximately the same time each day. Each capsule should be swallowed whole with fluid and not divided, crushed, chewed, or placed in water. The dosage should be reduced to half in patients with renal and hepatic impairment.

In case of overdose
In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose
Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications

This drug is contraindicated in the following conditions:

- Hypersensitivity to any of the components
- Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs)

Precautions

-The possibility of a suicide attempt is inherent in major depressive disorder and may persist until significant remission occurs. Close supervision of high-risk patients should accompany initial drug therapy until significant improvement in depression is observed.

-Do not stop taking this medicine without first checking with your doctor. Antidepressants should be withdrawn gradually (over at least one week after more than one week's therapy) to reduce the risk of withdrawal symptoms.

-The doctor should be informed in case of emergence of anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness or other unusual changes in the patient's behavior.

-Caution should be taken when driving a car or operating dangerous machinery until you know how you respond to the drug.

-This drug should not be used in patients with an identified very high risk of a serious ventricular arrhythmia or uncontrolled hypertension. Caution is advised in those with a recent history of myocardial infarction or whose condition might be exacerbated by an increase in heart rate.

-This drug should be used with caution in patients with hepatic or renal impairment and dosage adjustment may be necessary.

-This drug should be used with caution in patients with a history of epilepsy, in patients with a history of bleeding disorders or with hypomania or mania.

-Patients with raised intra-ocular pressure or at risk of angle-closure glaucoma should be monitored closely.

-Patients who develop a rash, urticaria, or related allergic reaction with this drug should be advised to contact their doctor.

-Inform your doctor before using this medication in case of pregnancy or lactation. This drug should be used during pregnancy only if clearly needed. This drug should not be used in nursing mothers.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

This drug should not be used in combination with a MAOI, or within 14 days of discontinuing treatment with a MAOI. At least 7 days should be allowed after stopping venlafaxine before starting an MAOI.

It is advised to avoid alcohol while taking this medication.

Caution should be taken when administered concomitantly with NSAIDs, aspirin, oral anticoagulants or other drugs that affect coagulation, with triptans, tramadol, tryptophan supplements or other serotonergic agents.

Adverse reactions

The most reported adverse reactions include: nausea, headache, hypertension, insomnia, somnolence, dry mouth, dizziness, constipation, sexual dysfunction, asthenia, sweating, nervousness, anorexia, hyponatremia, serum cholesterol elevation, allergic reactions

Other common adverse effects have included diarrhea, dyspepsia, abdominal pain, anxiety, urinary frequency, visual disturbances, mydriasis, vasodilatation, vomiting, tremor, paraesthesia, hypertonia, chills or fever, palpitations, weight gain or loss, agitation, confusion, arthralgia, myalgia, tinnitus, dyspnoea.

Aggressive behavior has developed particularly at the start and when stopping therapy.

Inform your doctor if any side effect appears or becomes bothersome.

Storage
Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children.
The expiry date is printed on the pack; don’t use this medicine after this date.

Pack Presentation
DEFAXINE, venlafaxine 75 mg, pack of 14 extended release capsules

Issue date: 02/2010
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