

## Depefex® 75 mg XL Capsules Depefex® 150 mg XL Capsules (Venlafaxine)

### SIX IMPORTANT THINGS YOU NEED TO KNOW ABOUT DEPEFEX

- **Depefex treats depression.** Like all medicines it can also have unwanted effects. It is important that you and your doctor discuss the benefits of taking Depefex and the harmful effects before you start treatment.
- **Depefex are not for use in children and adolescents under 18.** See section 2 of the leaflet.
- **Some people who are depressed think of harming or killing themselves.** If you start to feel worse, or think of harming or killing yourself, **see your doctor or go to a hospital straight away.** See section 2, **Thoughts of harming yourself.**
- **Depefex will not work straightaway.** Some people taking the medicine feel worse before feeling better. Your doctor should see you a few weeks after starting treatment. Tell your doctor if you do not feel better. See section 3, **How to take Depefex.**
- **Do not stop taking Depefex without talking to your doctor.** If you stop taking Depefex suddenly or miss a dose, you may get withdrawal effects. See section 3, **If you stop taking Depefex.**
- **If you are pregnant or planning to get pregnant, talk to your doctor.** See section 2 **Pregnancy and Breast-feeding**

### 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 Depefex is and what it is used for**
2. **What you need to know before you take Depefex**
3. **How to take Depefex**
4. **Possible side effects**
5. **How to store Depefex**
6. **Contents of the pack and other information**

The name of this medicine is Depefex 75 mg XL Capsules and Depefex 150 mg XL Capsules. For convenience, this leaflet will call it Depefex

## 1. WHAT DEPEFEX IS AND WHAT IT IS USED FOR

Depefex belongs to a group of medicines called **antidepressants**. They are one of a group of medicines called a selective serotonin and noradrenaline reuptake inhibitor (SNRI). It is thought that people who are depressed have lower levels of serotonin and noradrenaline in the brain. It is not fully understood how antidepressants work, but they may help by increasing the levels of serotonin and noradrenaline in the brain.

Depefex are used for the treatment of **depression**.

Your doctor may continue to give you Depefex when you are feeling better to stop your symptoms coming back or stop you becoming depressed in the future. Treating your depression properly is important to help you get better. If not treated your condition may not go away or may be more difficult to treat.

You may find it helpful to tell a friend or relative that you are depressed and ask them to read this leaflet as well. You might ask them to tell you if they are worried about any changes in your behaviour.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DEPEFEX

### DO NOT TAKE DEPEFEX IF:

- you have previously had an allergic reaction to venlafaxine or any of the other ingredients listed in section 6 at the end of this leaflet.
- you are also taking or have taken any time within the last 14 days any medicines known as irreversible monoamine oxidase inhibitors (MAOIs), used to treat depression or Parkinson's disease. Taking an irreversible MAOI together with other medicines, including Depefex can cause serious or even life-threatening side effects. Also, you must wait at least 7 days after you stop taking Depefex before you take any MAOI (see also the section "Taking Depefex with other medicines").

**If any of these apply to you, tell your doctor or pharmacist immediately, as the capsules may not be suitable for you.**

### USE IN CHILDREN AND ADOLESCENTS UNDER 18 YEARS OF AGE

Depefex should not normally be used in children and adolescents under the age of 18 years.

- Also, you should know that patients under 18 have an **increased risk of side effects** such as suicidal attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take this type of medicine. Despite this, your doctor may occasionally prescribe Depefex for patients under 18 because he/she decides that this is in their best interests.
- If your doctor has prescribed Depefex for someone under 18 and you want to discuss this, **please go back to your doctor.** You should inform your doctor if any of the symptoms listed above develop or worsen when patients under 18 are taking these capsules.
- The long-term safety effects of Depefex on growth, maturation and cognitive and behavioural development in this age group has not yet been demonstrated.

### Take special care and tell your doctor or pharmacist before taking Depefex if:

- You use other medicines that taken concomitantly with Depefex could increase the risk of developing serotonin syndrome (see the section "Taking Depefex with other medicines").
- You have a history of epilepsy, fits or seizures
- You suffer from, or have a history of, or if someone in your family has had, mania or bipolar disorder (feeling over-excited or euphoric).
- You have eye problems or suffer from, or have a history of, narrow angle glaucoma (increased pressure in the eye).
- You have a tendency to develop bruises or a tendency to bleed easily (history of bleeding disorders), or if you are taking other medicines that may increase the risk of bleeding or if you are pregnant (see Pregnancy, breast-feeding and fertility).
- You have a history of high blood pressure.
- You have a history of aggressive behaviour.
- You have a history of low sodium levels in your blood (hyponatraemia).
- You have a history of heart problems.
- You have been told you have an abnormal heart rhythm.
- You have diabetes (your blood glucose levels may be altered due to Depefex, therefore the dosage of your diabetes medicines may need to be adjusted).

Depefex may cause a sensation of restlessness or an inability to sit or stand still during the first few weeks of treatment. You should tell your doctor if this happens to you.

If you have any of the above, please talk with your doctor before taking Depefex.

### Thoughts of harming yourself:

People who are depressed can sometimes have thoughts of harming or killing themselves. These may be increased when you first start taking antidepressants since these medicines 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 get these thoughts at any time, contact your doctor or go to the nearest hospital straight away.

You may find it helpful to tell a relative or close friend that you are depressed, and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

### Dry Mouth

Dry mouth is reported in 10% of patients treated with venlafaxine. This may increase the risk of caries (tooth decay). Therefore, you should take special care in your dental hygiene.

### Sexual Problems

Medicines like Depefex (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

### Taking Depefex with other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Your doctor should decide whether you can take Depefex with other medicines.

Do not start or stop taking any medicines, including those bought without a prescription, natural and herbal remedies, before checking with your doctor or pharmacist.

- Monoamine oxidase inhibitors which are used to treat depression or Parkinson's disease must not be taken with Depefex XL. Tell your doctor if you have taken these medicines within the last 14 days. (MAOIs: see the section "Before you take Depefex").

- Serotonin syndrome:

Serotonin syndrome, a potentially life-threatening condition (see the section "Possible Side Effects"), may occur with venlafaxine treatment, particularly when taken with other medicines. Examples of these medicines include:

- Triptans (used for migraine)
- Medicines to treat depression, for instance SNRI, SSRI, tricyclics, or medicines containing lithium
- Medicines containing amphetamines (used to treat attention deficit hyperactivity disorder (ADHD), narcolepsy and obesity)
- Medicines containing linezolid, an antibiotic (used to treat infections)
- Medicines containing moclobemide, a MAOI (used to treat depression)
- Medicines containing sibutramine (used for weight loss)
- Medicines containing tramadol, fentanyl, tapentadol, pethidine, pentazocine (a pain-killer)
- Products containing St. John's Wort (also called Hypericum perforatum, a natural or herbal remedy used to treat mild depression)
- Products containing tryptophan (used for problems such as sleep and depression)
- Medicines containing dextromethorphan (used to treat coughing)
- Medicines containing methadone or buprenorphine (used to treat opioid drug addiction or severe pain)
- Medicines containing methylene blue (used to treat high levels of methaemoglobin in the blood)
- Antipsychotics (used to treat a disease with symptoms such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, unclear reasoning and becoming withdrawn).

Signs and symptoms of serotonin syndrome may include a combination of the following: restlessness, hallucinations, loss of coordination, fast heart beat, increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhoea, coma, nausea, vomiting, mental-status changes, autonomic instability, neuromuscular abnormalities, and/or gastrointestinal symptoms. In its most severe form, serotonin syndrome can resemble Neuroleptic Malignant Syndrome (NMS). Signs and symptoms of NMS may include a combination of fever, fast heart beat, sweating, severe muscle stiffness, confusion, increased muscle enzymes (determined by a blood test). Get medical care right away if you think serotonin syndrome is happening to you.

You must tell your doctor if you are taking medicines that can affect your heart rhythm.

Examples of these medicines include:

- Antiarrhythmics such as quinidine, amiodarone, sotalol or dofetilide (used to treat abnormal heart rhythm)
- Antipsychotics such as thioridazine (See also Serotonin syndrome above)
- Antibiotics such as erythromycin or moxifloxacin (used to treat bacterial infections)
- Antihistamines (used to treat allergy)

The following medicines may also interact with Depefex and should be used with caution. It is especially important to mention to your doctor or pharmacist if you are taking medicines containing:

- Ketoconazole (an antifungal medicine)
- Haloperidol or risperidone (to treat psychiatric conditions)
- Metoprolol (a beta blocker to treat high blood pressure and heart problems).

### Taking Depefex with food, drink and alcohol

You should swallow each capsule whole with food and with a drink of water.

**You should avoid drinking alcohol** while you are taking the capsules. Alcohol may make your symptoms or side effects worse.

### Pregnancy, breast-feeding and fertility

You must tell your doctor if you are pregnant or breast-feeding, think you may be pregnant or plan to become pregnant, so that another medicine can be considered. You should use Depefex only after

discussing the potential benefits and the potential risks to your unborn child with your doctor.

Make sure your midwife and/or doctor know you are on Depefex. When taken during pregnancy, similar drugs (SSRIs) may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the new born (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hour after the baby is born. If this happens to your baby or if your baby is not feeding properly or has trouble breathing, you should contact your midwife and/or doctor immediately. If you take Depefex near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking Depefex so they can advise you. Breast-feeding is not recommended as venlafaxin in Depefex can pass into the breast milk, and there would be risk of an effect on the baby. Therefore, you should discuss this matter with your doctor, and he/she will decide whether you should stop breast-feeding or stop the therapy with Depefex.

#### Driving and using machines

Possible side effects of Depefex are dizziness, confusion and eye sight changes such as blurred vision. If you get these or feel that your judgement, thinking or co-ordination is affected when you take Depefex do not drive or use machines.

#### Important information about some of the ingredients of Depefex

This product contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking the medicinal product.

### 3. HOW TO TAKE DEPEFEX

**Always take Depefex exactly as your doctor has told you.** You should check with your doctor or pharmacist if you are not sure.

**The usual starting dose is one 75 mg capsule a day.** However, your doctor may start with a different dose, particularly if you are elderly or have liver or kidney problems. Your doctor may also change your dose during the course of your treatment. Your dose can be raised by your doctor gradually, and if needed, even up to a maximum dose of 375 mg daily for depression.

You should swallow each capsule whole at approximately the same time each day, either in the morning or evening. **Do not** break open, crush or chew the capsules, or put them in water before swallowing.

Depefex should be taken with food. Do not stop taking Depefex without talking to your doctor (see the section "If you stop taking Depefex").

#### If you take more Depefex than you should

Never take more capsules than your doctor tells you. If you accidentally take too many capsules contact your doctor or hospital immediately. Remember to take the packet with you, even if it is empty.

The symptoms of a possible overdose may include a rapid heart beat, changes in level of alertness (ranging from sleepiness to coma), blurred vision, seizures or fits, and vomiting.

#### If you forget to take Depefex

If you forget to take a capsule, you can take it up to 12 hours after you usually take it, and then take your next capsule at the usual time. If the period after the missed dose is more than 12 hours, you should miss the dose altogether and just take your next capsule at the usual time.

Do not take a double dose to make up for a forgotten capsule.

#### If you stop taking Depefex

**Do not** stop taking your capsules or reduce the dose without the advice of your doctor, even if you feel better. If your doctor thinks you no longer need Depefex, your dose will be reduced gradually before stopping treatment altogether.

Side effects are known to occur when people stop using Depefex, especially when the capsules are stopped suddenly or the dose reduced too quickly. Some patients may experience symptoms such as: tiredness, dizziness, light-headedness, headache, sleeplessness, nightmares, dry mouth, loss of appetite, feeling or being sick, diarrhoea, nervousness, agitation, confusion, tinnitus (ringing in the ears), tingling, weakness, sweating, fits/seizures, or flu-like symptoms. These symptoms are generally non-serious and disappear within a few days.

Your doctor will advise you on how you should gradually stop Depefex and if you suffer any of these or other symptoms that are troublesome, return to your doctor for further advice.

If you require any further information on Depefex please consult your doctor or pharmacist.

### 4. POSSIBLE SIDE EFFECTS

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

**Do not be concerned if you see small white granules or balls in your stools after taking Depefex. Inside Depefex capsules are spheroids or small white balls that contain the venlafaxine active ingredient. These spheroids are released from the capsule into your gastrointestinal tract. As the spheroids travel the length of your gastrointestinal tract, venlafaxine is slowly released. The spheroid "shell" remains undissolved and is eliminated in your stools. Therefore, even though you may see spheroids in your stools, your dose of venlafaxine has been absorbed.**

Although the frequency cannot be estimated from the available data cases of suicidal ideation and suicidal behaviours have been reported during venlafaxine therapy or early after treatment discontinuation (see section 2, What you need to know before you take Depefex XL).

If any of the following happen, do not take more Depefex XL. **Tell your doctor immediately, or go to the casualty department at your nearest hospital:**

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

- Swelling of the face, mouth, tongue, throat, hands, or feet, and/or a raised itchy rash (hives), trouble swallowing or breathing

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

- Chest tightness, wheezing, trouble swallowing or breathing
- Severe skin rash, itching or hives (elevated patches of red or pale skin that often itch)
- Signs and symptoms of serotonin syndrome which may include restlessness, hallucinations, loss of coordination, fast heart beat, increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhoea, coma, nausea vomiting, mental-status changes, autonomic instability, neuromuscular abnormalities, and/or gastrointestinal symptoms.

In its most severe form, serotonin syndrome can resemble Neuroleptic Malignant Syndrome (NMS).

Signs and symptoms of NMS may include a combination of fever, fast heart beat, sweating, severe muscle stiffness, confusion, increased muscle enzymes (determined by a blood test).

- Signs of infection, such as high temperature, chills, shivering, headaches, sweating, flu-like symptoms. This may be the result of a blood disorder which leads to an increased risk of infection.

- Severe rash, which may lead to severe blistering and peeling of the skin.
- Unexplained muscle pain, tenderness or weakness. This may be a sign of rhabdomyolysis.

#### Frequency not known (cannot be estimated from the available data)

- Signs and symptoms of a condition called "stress cardiomyopathy" which may include chest pain, shortness of breath, dizziness, fainting, irregular heartbeat.

#### Other reported side effects

##### Very common (affects more than 1 person in 10 users):

- headache; dizziness; drowsiness
- insomnia
- nausea; dry mouth; constipation
- sweating (including night sweats)

##### Common (affects less than 1 person in 10 users):

- weight loss; weight gain; increased cholesterol
- abnormal dreams; decreased libido; increased muscle tonus; nervousness; pins and needles; tremor; confusion; feeling separated (or detached) from yourself; agitation; a sensation of restlessness or an inability to sit or stand still; altered taste sensation
- blurred vision; dilated pupils; inability of the eye to automatically change focus from distant to near objects
- increase in blood pressure; flushing; palpitations; fast heartbeat
- yawning; shortness of breath
- appetite decreased; vomiting; diarrhoea
- difficulties passing urine; increased frequency in urination; inability to pass urine
- abnormal ejaculation/orgasm (males); lack of orgasm; erectile dysfunction (impotence); menstrual irregularities such as increased bleeding or increased irregular bleeding
- weakness (asthenia); chills; fatigue
- ringing in the ears (tinnitus)
- mild rash; itching

##### Uncommon (affects less than 1 person in 100 users):

- bruising; vomiting blood; black tarry stools (faeces) or blood in stools, which can be a sign of internal bleeding
- lack of feeling or emotion; hallucinations; involuntary movement of the muscles; impaired coordination and balance
- feeling dizzy (particularly when standing up too quickly), fainting, decrease in blood pressure
- grinding of the teeth; feeling separated (or detached) from reality; feeling over-excited
- abnormal hair loss
- abnormal orgasm (females)
- sensitivity to sunlight
- over activity, racing thoughts and decreased need for sleep (mania)
- inability to control urination
- stiffness, spasms and involuntary movements of the muscles
- slight changes in blood levels of liver enzymes

##### Rare (affects less than 1 person in 1000 users):

- seizures or fit
- coughing, wheezing and shortness of breath which may be accompanied by a high temperature
- disorientation and confusion often accompanied by hallucination (delirium)
- excessive water intake (known as SIADH)
- decrease in blood sodium levels
- severe eye pain and decreased or blurred vision
- abnormal, rapid or irregular heartbeat, which could lead to fainting
- severe abdominal or back pains (which could indicate a serious problem in the gut, liver or pancreas)
- itchininess, yellow skin or eyes, dark urine, or flu-like symptoms, which are symptoms of inflammation of the liver (hepatitis)
- Dystonia - muscle disorder causing twisting movements (dystonia)

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

- prolonged bleeding, which may be a sign of reduced number of platelets in your blood, leading to an increased risk of bruising or bleeding
- abnormal breast milk production
- unexpected bleeding, e.g. bleeding gums, blood in the urine or in vomit, or the appearance of unexpected bruises or broken blood vessels (broken veins)
- Tardive dyskinesia - uncontrollable movements of mouth, tongue and limbs (tardive dyskinesia)

##### Not known (frequency cannot be estimated from the available data):

- aggression
- vertigo
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy, breast-feeding and fertility in section 2 for more information

Depefex sometimes causes unwanted effects which you may not be aware of, such as increases in blood pressure or abnormal heart beat, or slight changes in blood levels of liver enzymes, sodium or rarely cholesterol (fats). More rarely, Depefex may reduce the function of platelets in your blood, leading to increased chance of bruising or bleeding. Therefore, your doctor may wish to do blood tests occasionally, particularly if you have been taking the capsules for a long time.

#### 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](http://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 medicine.

### 5. HOW TO STORE DEPEFEX

Keep this medicine out of the sight and reach of children.

Do not use Depefex after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not store Depefex above 25°C. Store in the original package in order to protect from light. Medicines should not be disposed of via wastewater or household waste. Ask your Pharmacist how to dispose of medicines no longer required.

### 6. CONTENTS OF THE PACK AND OTHER INFORMATION

#### What Depefex Capsules contain

Each Capsule contains 75 mg or 150 mg of venlafaxine as venlafaxine hydrochloride. The other ingredients in the capsules are: stearic acid, ethylcellulose, talc, gelatin, sucrose and maize starch. The 75mg capsules also contain Titanium dioxide

#### What Depefex Capsules look like and contents of the pack

Depefex Capsules come in two strengths. Depefex 75 mg XL Capsules are white opaque capsules containing white or whitish pellets. Depefex 150 mg XL Capsules are natural transparent capsules containing white or whitish pellets. They come in packs containing 28 capsules.

#### Marketing Authorisation Holder and Manufacturer

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