

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Vensir XL 75mg Prolonged-Release Capsules Venlafaxine Hydrochloride

#### IMPORTANT THINGS YOU SHOULD KNOW ABOUT VENSIR XL

Please read all of this leaflet before you start to take your medicine as it contains important information about Vensir XL.

- **Vensir XL is used to treat depression, severe and persistent anxiety known as generalised anxiety disorder (GAD), social anxiety disorder (also known as social phobia) and panic disorder (panic attacks).**
- **Vensir XL is not for use in children and adolescents** – see in section 2 ‘Children and adolescents’.

**If you have any concerns about how you feel, or about this medication, it is important that you talk to your doctor – even if you feel anxious or worried about doing so.**

You may find it helpful to tell a friend or relative that you are depressed or suffering from an anxiety disorder, and that you have been prescribed this medication; it might be useful to show them this leaflet.

- **Vensir XL may not start to work immediately.**  
Some people taking antidepressants may feel worse before feeling better. Your doctor may ask to see you again a couple of weeks after you start treatment and then regularly until you start to feel well again. Tell your doctor if you do not start to feel better.
- **Some people who are depressed may think of harming or killing themselves. If this happens you should see your doctor or go to a hospital straight away** – see in section 2 ‘Thoughts of suicide and worsening of your depression or anxiety disorder’.
- **If you take too many capsules it is important to seek immediate medical attention, even if you feel well, because of the risk of serious side effects.**
- **Do not stop taking Vensir XL or change your dose without the advice of your doctor even if you feel better.** If you stop taking Vensir XL abruptly you may get withdrawal reactions – see in section 3 ‘If you stop taking Vensir XL’.
- **If you have heart problems such as fast or irregular heart rate or high blood pressure you should talk to your doctor before taking Vensir XL** – see in section 2 ‘Before you take Vensir XL’.
- **Taking certain other medicines with Vensir XL may cause problems. You should tell your doctor if you are taking any other medicines** – see in section 2 ‘What you need to know before you take Vensir XL’.
- **See your doctor without delay** if you feel restless and feel like you can’t keep still, feel ‘high’ or very over-excited, have jerky muscle movements which you can’t control. See section 4 – ‘Possible side effects’ for other important information.

**If you are pregnant, or intend to become pregnant, or breast-feeding, you should talk to your doctor – see in section 2 ‘Pregnancy and breast-feeding’.**  
**More information on all of these points is provided in the rest of this leaflet.**

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

## **1. What Vensir XL is and what it is used for**

Vensir XL contains the active substance venlafaxine. Vensir XL is an antidepressant that belongs to a group of medicines called serotonin and norepinephrine reuptake inhibitors (SNRIs). This group of medicines is used to treat depression and other conditions such as anxiety disorders. It is not fully understood how antidepressants work, but they may help by increasing the levels of serotonin and noradrenaline in the brain.

Vensir XL is a treatment for adults with depression. It is also a treatment for adults with the following anxiety disorders: generalized anxiety disorder, social anxiety disorder (fear or avoidance of social situations) and panic disorder (panic attacks). Treating depression or anxiety disorders properly is important to help you get better. If it is not treated, your condition may not go away and may become more serious and more difficult to treat.

## **2. What you need to know before you take Vensir XL**

**Do not use Vensir XL if:**

- If you are allergic to venlafaxine or any of the other ingredients of this medicine (listed in section 6).
- If you are also taking, or have taken 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 Vensir XL, can cause

serious or even life-threatening side effects. Also, you must wait at least 7 days after you stop taking Vensir XL before you take any MAOI (see also the section entitled “Other medicines and Vensir XL” and the information in that section about ‘Serotonin Syndrome’).

### **Warning and precautions:**

Talk to your doctor or pharmacist before taking Vensir XL

Do not drink alcohol while being treated with Vensir XL as this medicine can lead to extreme tiredness and unconsciousness. Concomitant use with alcohol and/or certain medicines can make your symptoms of depression and other conditions, such as anxiety disorders worse.

### **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 you first start taking antidepressants, since these medicines all take time to work, usually about two weeks, but sometimes longer. These thoughts may also occur when your dose is decreased or during discontinuation of treatment with Vensir XL.

You may be more likely to think like this if you:

- have previously had thoughts about killing yourself or harming yourself
- are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in young adults (less than 25 years old) 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.

Talk to your doctor **before** taking Vensir XL if you:

- use other medicines that taken together with Vensir XL could increase the risk of developing serotonin syndrome, a potentially life-threatening condition (see the section “Other medicines and Vensir XL”).
- have eye problems, such as certain kinds of glaucoma (increased pressure in the eye).
- have a history of high blood pressure.
- have a history of heart problems.
- have been told you have an abnormal heart rhythm.
- have a history of fits (seizures).
- have a history of low sodium levels in your blood (hyponatraemia).
- 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 e.g., warfarin (used to prevent blood clots), or if you are pregnant (see *'Pregnancy and breast-feeding'*).

- have a history of, or if someone in your family has had, mania or bipolar disorder (feeling over-excited or euphoric).
- have a history of aggressive behaviour
- have diabetes.

Vensir XL 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.

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

### **Dry mouth**

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

### **Diabetes**

Your blood glucose levels may be altered due to Vensir XL. Therefore, the dosage of your diabetes medicines may need to be adjusted.

### **Children and adolescents**

Vensir XL should normally not be used for children and adolescents under 18 years. Also, you should know that patients under 18 have an increased risk of side-effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe this medicine for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed this medicine for a patient 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 Vensir XL. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of this medicine in this age group has not yet been demonstrated.

### **Other medicines and Vensir XL**

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

Your doctor should decide whether you can take Vensir XL 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 Vensir XL**. Tell your doctor if you have taken these medicines within the last 14 days. (MAOIs: see the section "What you need to know before you take Vensir XL").
- **Serotonin syndrome:**

A potentially life-threatening condition or Neuroleptic Malignant Syndrome (NMS)-like reactions (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)
- Other medicines to treat depression, for instance SNRIs, SSRIs, 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 opioids e.g. buprenorphine, tramadol, fentanyl, tapentadol, pethidine, or pentazocine (used to treat severe pain)
- Medicines containing dextromethorphan (used to treat coughing)
- Medicines containing methadone (used to treat opioid drug addiction or severe pain)
- Medicines containing methylene blue (used to treat high levels of methaemoglobin in the blood)
- 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)
- Antipsychotics, such as clozapine (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 heartbeat, increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhoea, coma, nausea, vomiting.

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 heartbeat, sweating, severe muscle stiffness, confusion, increased muscle enzymes (determined by a blood test).

**Tell your doctor immediately, or go to the casualty department at your nearest hospital 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 Vensir XL 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 Vensir XL with food, drink and alcohol**

Food:

The capsules should be taken with food (see section 3 “How to take Vensir XL”).

Alcohol:

Do not drink alcohol while being treated with Vensir XL. Concomitant use with alcohol can lead to extreme tiredness and unconsciousness and can make your symptoms of depression and other conditions, such as anxiety disorders worse.

### **Pregnancy and breast-feeding**

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. You should use Vensir XL 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 Vensir XL. 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 hours after the baby is born. If this happens to your baby, you should contact your midwife and/or doctor immediately.

If you are taking this medicine during pregnancy, other symptoms your baby might have when it is born is not feeding properly, in addition to having trouble breathing. If your baby has these symptoms when it is born, and you are concerned, contact your doctor and/or midwife who will be able to advise you.

If you take Vensir XL 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 Vensir XL so they can advise you. Vensir XL passes into breast milk. There is a risk of an effect on the baby. Therefore, you should discuss the matter with your doctor, and he/she will decide whether you should stop breast-feeding or stop the therapy with this medicine.

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

### **Driving and using machines**

Do not drive or use any tools or machines until you know how this medicine affects you

### **Important information about some of the ingredients of Vensir XL**

#### **3. How to take Vensir XL**

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

The recommended starting dose for the treatment of depression, generalised anxiety disorder and social anxiety disorder is 75mg per day. The dose can be raised by your doctor gradually, and if needed, even up to a maximum dose of 375 mg daily for depression. If you are being treated for panic disorder, your doctor will start with a lower dose (37.5 mg) and then increase the dose gradually. The maximum dose for generalised anxiety disorder, social anxiety disorder and panic disorder is 225 mg/day.

Take Vensir XL at approximately the same time each day, either in the morning or in the evening. Capsules must be swallowed whole with fluid and not opened, crushed, chewed or dissolved.

Vensir XL should be taken with food. If you have liver or kidney problems, talk to your doctor, since your dose of this medicine may need to be different.

Do not stop taking this medicine without talking to your doctor (see the section “If you stop taking Vensir XL”).

#### **Children and adolescents**

The use of Vensir XL in children and adolescents (under the age of 18) is not recommended (see also section 2).

#### **Impairment of the liver or kidneys**

If you suffer from liver or kidney problems, the dosage may be reduced by your doctor.

#### **If you take more Vensir XL than you should**

Call your doctor or pharmacist immediately if you take more of this medicine than the amount prescribed by your doctor.

Overdose can be life-threatening, especially with concomitant use of alcohol and/or certain medicines (see “Other medicines and Vensir XL”).

Symptoms of overdose: A rapid heartbeat, changes in level of alertness (ranging from sleepiness to coma), blurred vision, seizures or fits, and vomiting.

#### **If you forget to take Vensir XL**

If you miss a dose, take it as soon as you remember. However, if it is time for your next dose, skip the missed dose and take only a single dose as usual. Do not take a double dose to make up for a forgotten dose. Do not take more than the daily amount of Vensir XL that

has been prescribed for you in one day.

### **If you stop taking Vensir XL**

Do not stop taking your treatment or reduce the dose without the advice of your doctor even if you feel better. If your doctor thinks that you no longer need Vensir XL, he/she may ask you to reduce your dose slowly before stopping treatment altogether. Side effects are known to occur when people stop using this medicine, especially when it is stopped suddenly, or the dose is reduced too quickly. Some patients may experience symptoms such as suicidal thoughts, aggressiveness, tiredness, dizziness, light-headedness, headache, sleeplessness, nightmares, dry mouth, loss of appetite, nausea, diarrhoea, nervousness, agitation, confusion, ringing in the ears, tingling or rarely electric shock sensations, weakness, sweating, seizures, or flu-like symptoms, problems with eyesight and increase in blood pressure (which can cause headache, dizziness, ringing in the ears, sweating, etc). Your doctor will advise you on how you should gradually discontinue Vensir XL treatment. If you experience any of these or other symptoms that are troublesome, ask your doctor for further advice. 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 any of the following happen, do not take more Vensir 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 heartbeat, increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhoea, coma, nausea, vomiting. 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 heartbeat, 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 side effects that you should tell your doctor about include (The frequency of these side effects are included in the list ‘Other side effects that may occur’ below):

- Coughing, wheezing and shortness of breath which may be accompanied by a high temperature
- Black (tarry) stools or blood in stools
- Itchiness, yellow skin or eyes, or dark urine, which may be symptoms of inflammation of the liver (hepatitis)
- Heart problems, such as fast or irregular heart rate, increased blood pressure
- Eye problems, such as blurred vision, dilated pupils
- Nerve problems, such as dizziness, pins and needles, movement disorder (muscle spasms or stiffness), seizures or fits
- Psychiatric problems, such as hyperactivity and feeling unusually overexcited
- Withdrawal effects (see the section ‘How to take Vensir XL, if you stop taking Vensir XL’)

Prolonged bleeding - if you cut or injure yourself, it may take slightly longer than usual for bleeding to stop.

**Do not be concerned if you see small white balls or granules in your stools after taking this medicine. Inside Vensir XL capsules are spheroids (small white balls) that contain the active ingredient (venlafaxine). These spheroids are released from the capsule into your stomach. As they travel through your stomach and intestines, venlafaxine is slowly released. The spheroid “shell” does not dissolve and is passed out in your stools. So, even though you may see spheroids in your stools, your dose of medicine has been absorbed.**

**Other side effects that may occur**

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

- Headache, drowsiness, dizziness
- Insomnia
- dry mouth, constipation, nausea
- Sweating (including night sweats)

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

- Appetite decreased
- Confusion; feeling separated (or detached) from yourself; lack of orgasm; decreased libido; agitation; nervousness; abnormal dreams
- Tremor; a sensation of restlessness or an inability to sit or stand still; pins and needles; altered taste sensation; increased muscle tonus
- Visual disturbance including blurred vision; dilated pupils; inability of the eye to automatically change focus from distant to near objects
- Ringing in the ears (tinnitus)

- Fast heartbeat; palpitations
- Increase in blood pressure; flushing
- Shortness of breath; yawning
- Vomiting; diarrhoea
- Mild rash; itching
- Increased frequency in urination; inability to pass urine; difficulties passing urine
- Menstrual irregularities such as increased bleeding or increased irregular bleeding; abnormal ejaculation/ orgasm (males); erectile dysfunction (impotence)
- Weakness (asthenia); fatigue; chills
- Weight gain; weight loss
- Increased cholesterol
- Sedation

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

- Over activity, racing thoughts and decreased need for sleep (mania)
- Hallucinations; feeling separated (or detached) from reality; abnormal orgasm; lack of feeling or emotion; feeling over-excited; grinding of the teeth
- Fainting; involuntary movements of the muscles; impaired coordination and balance
- Feeling dizzy (particularly when standing up too quickly); decrease in blood pressure
- Vomiting blood, black tarry stools (faeces) or blood in stools; which can be a sign of internal bleeding
- Sensitivity to sunlight; bruising; abnormal hair loss
- Inability to control urination
- Stiffness, spasms and involuntary movements of the muscles
- Slight changes in blood levels of liver enzymes
- Agitation

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

- Seizures or fits
- Coughing, wheezing and shortness of breath which may be accompanied by a high temperature which are symptoms of inflammation of the lungs associated with an increase in white blood cells (pulmonary eosinophilia)
- 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)
- Itchiness, yellow skin or eyes, dark urine, or flu-like symptoms, which are symptoms of inflammation of the liver (hepatitis)

**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)

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

- Suicidal ideation and suicidal behaviours; 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 Vensir XL)
- Aggression
- Vertigo
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see ‘Pregnancy and breast-feeding’ in section 2 for more information.

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

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

UK:

Yellow Card Scheme

Website: [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.

Ireland:

HPRA Pharmacovigilance,

Website: [www.hpra.ie](http://www.hpra.ie);

Malta

ADR Reporting Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal).

**5. How to store Vensir XL**

Do not store above 25°C.

Store in the original container to protect from moisture.

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

Do not use Vensir XL if you notice that the capsules are sticky or other visible signs of deterioration.

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 Vensir XL capsules contains**

The active substance is venlafaxine hydrochloride equivalent to 75mg venlafaxine.

The other ingredients are: microcrystalline cellulose, copovidone, ethyl cellulose, magnesium stearate, povidone, colloidal silicon dioxide, talc.

The capsule shell for 75mg contains gelatine, titanium dioxide (E171), black iron oxide (E172), red iron oxide (E172). The printing ink contains the following: shellac, propylene glycol, red iron oxide (E172).

The active substance and ingredients are used to make white to off-white round biconvex film coated mini tablets of 12.5mg. The 75mg capsule contains 6 mini tablets.

### **What Vensir XL capsules look like and contents of the pack**

The 75mg capsules are opaque, peach coloured, prolonged release hard capsules having red coloured thick and thin radial circular bands on both ends of the capsules.

Vensir XL capsules are available in blister packs of 10, 14, 15 20, 28, 30, 56, 60 or 100 capsules.

Not all pack sizes may be marketed

### **Marketing Authorisation Holder**

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