

Package leaflet: Information for the user
Tonpular XL 75mg Prolonged-Release Hard Capsules
Tonpular XL 150mg Prolonged-Release Hard Capsules
Venlafaxine 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 Tonpular XL is and what it is used for**
- 2. What you need to know before you take Tonpular XL**
- 3. How to take Tonpular XL**
- 4. Possible side effects**
- 5. How to store Tonpular XL**
- 6. Contents of the pack and other information**

1. What Tonpular XL is and what it is used for

Tonpular XL contains the active substance venlafaxine hydrochloride.

Tonpular XL is an antidepressant that belongs to a group of medicines called Serotonin and Noradrenaline Reuptake Inhibitors (SNRIs). This group of medicines is used to treat depression and other conditions such as anxiety disorders. It is thought that people who are depressed and/or anxious 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.

Tonpular XL is a treatment for adults with depression. It is also a treatment for adults with the following anxiety disorders: generalised 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 Tonpular XL

Do not take Tonpular XL:

- if you are allergic to venlafaxine or to 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 medicine known as irreversible monoamine oxidase inhibitors (MAOIs), used to treat depression or Parkinson's disease. Taking an irreversible MAOI together with Tonpular XL, can cause serious or even life-threatening side effects. Also, you must wait at least 7 days after you stop taking Tonpular XL before you take any MAOI (see also the section entitled "Other medicines and Tonpular XL and the information in that section about 'Serotonin Syndrome').

Warning and precautions

Talk to your doctor or pharmacist **before taking** Tonpular XL:

- If you use other medicines that taken together with Tonpular XL could increase the risk of developing serotonin syndrome (see "Other medicines and Tonpular XL").
- If you have eye problems, such as certain kinds of glaucoma (increased pressure in the eye).
- If you have a history of high blood pressure.
- If you have a history of heart problems.
- If you have been told you have an abnormal heart rhythm.
- If you have a history of fits (seizures).

- If you have a history of low sodium levels in your blood (hyponatraemia).
- If 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 e.g., warfarin (used to prevent blood clots).
- If you have a history of, or if someone in your family has had, mania or bipolar disorder (feeling over-excited or euphoric).
- If you have a history of aggressive behaviour.

Tonpular XL may cause a sensation of restlessness or an inability to sit or stand still. You should tell your doctor if this happens to you.

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
- you are a young adult. Information from clinical trials has shown an increased risk in suicidal behaviour in adults (aged less than 25 years) with psychiatric conditions who were treated with an antidepressant.

If you have thoughts about harming or killing yourself at any time, contact your doctor or go to hospital straight away.

You may find it helpful to tell a close friend or relative 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.

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 Tonpular XL. Therefore, the dosage of your diabetes medicines may need to be adjusted.

Children and adolescents

This medicine 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 Tonpular 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 Tonpular XL

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

Your doctor should decide whether you can take Tonpular 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 Tonpular 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 Tonpular 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 used to treat depression such as SNRI, 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 reversible MAOI (used to treat depression)
- medicines containing sibutramine (used for weight loss)
- medicines containing 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 (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.

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).

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 Tonpular 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)

Tonpular XL with food, drink and alcohol

Tonpular XL should be taken with food (see section 3 "How to take Tonpular XL").

You should avoid alcohol while taking this medicine.

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 Tonpular 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 Tonpular 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, in addition to having trouble breathing, another symptom your baby might have when it is born is not feeding properly. 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.

Tonpular 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.

Driving and using machines

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

Tonpular XL 75mg capsules contain sunset yellow FCF (E110), carmoisine (E122) and allura red AC (E129). These azo colouring agents may cause allergic reactions.

Tonpular XL 150mg capsules contain sunset yellow FCF (E110) and tartrazine (E102). These azo colouring agents may cause allergic reactions.

3. How to take Tonpular XL

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

The usual recommended starting dose for treatment of depression, generalised anxiety disorder and social anxiety disorder is 75 mg 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 Tonpular 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.

Tonpular 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 Tonpular XL ”).

If you take more Tonpular XL than you should

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

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 Tonpular 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 Tonpular XL that has been prescribed for you in one day.

If you stop taking Tonpular 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 Tonpular 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 Tonpular XL especially when Tonpular XL is stopped suddenly or the dose is reduced too quickly. Some patients may experience symptoms such as 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.

Your doctor will advise you on how you should gradually discontinue Tonpular 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 product, 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 Tonpular 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.
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.

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, shortness of breath and 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 Tonpular XL , if you stop taking Tonpular 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 granules or balls in your stools after taking Tonpular XL. Inside Tonpular XL 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.

Other side effects that may occur

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

- dizziness; headache; drowsiness

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

Common (may affect up to 1 in 10 people)

- decreased appetite
- 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 tone
- 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
- difficulties passing urine; increased frequency in urination; inability to pass 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

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 (females); lack of feeling or emotion; feeling over-excited; grinding of the teeth
- fainting; involuntary movement 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

Rare (may affect up to 1 in 1000 people)

- seizures or fits
- 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)
- 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 Tonpular XL)
- aggression
- vertigo

Tonpular 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, Tonpular 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 Tonpular XL 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 national reporting systems listed below.

United Kingdom

Yellow Card Scheme

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2.

Tel: +353 1 6764971, Fax: +353 1 6762517

Website: www.hpra.ie, e-mail: medsafety@hpra.ie

Malta

ADR Reporting

www.medicinesauthority.gov.mt/adrportal

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

5. How to store Tonpular XL

- 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 packaging. The expiry date refers to the last day of that month.
- Store below 25°C. Store in the original package to protect from moisture.

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 Tonpular XL contains**

The active substance is venlafaxine: Each prolonged release hard capsule contains 84.8mg of venlafaxine hydrochloride, equivalent to 75mg venlafaxine or 169.7mg venlafaxine hydrochloride, equivalent to 150mg venlafaxine.

The other ingredients are:

Contents of the capsule: microcrystalline cellulose, povidone K 30, ethylcellulose, triethyl citrate, talc, methacrylic acid copolymer Type C, sodium bicarbonate, colloidal anhydrous silica, sodium laurilsulfate

Capsule shell: titanium dioxide (E171), sunset yellow FCF (E110), brilliant blue FCF (E133), gelatin, sodium laurilsulfate, shellac.

75mg strength capsule shell also contain: carmoisine (E122), povidone and allura red (E129).

150mg strength capsule shell also contain: tartrazine (E102).

What Tonpular XL look like and the contents of the pack

Tonpular XL 75mg Prolonged-Release Hard Capsules are a hard gelatine capsule with light pink opaque cap and light pink opaque body filled with white to off white pellets, imprinted with W 717 on cap in red colour.

Tonpular XL 150mg Prolonged-Release Hard Capsules are a hard gelatine capsule with orange opaque cap and orange opaque body filled with white to off white pellets, imprinted with W7 18 on cap in white colour.

Both strengths are supplied in a blister pack and outer cardboard carton, and are available in pack size of 14 or 28 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder: Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham LL13 9UF, UK. These medicinal products are authorised in the Member States of the EEA under the following names:

UK: Tonpular XL 75mg or 150mg Prolonged-Release Hard Capsules

Ireland: Tonpular XL 75mg or 150mg Prolonged-Release Hard Capsules

Poland: Tonpular PR 75mg or 150mg Prolonged-Release Capsules, Hard

Cyprus: Tonpular XL 75mg or 150mg Prolonged-Release Hard Capsules

Malta: Tonpular XL 75mg or 150mg Prolonged-Release Hard Capsules

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only).

Please be ready to give the following information:

Product name	Reference number
Tonpular XL 75mg Prolonged-Release Hard Capsules	29831/0364
Tonpular XL 150mg Prolonged-Release Hard Capsules	29831/0365

This is a service provided by the Royal National Institute of Blind People

For the Republic of Ireland please call +44 1978 661261

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