PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986 The medicine is dispensed with a doctor's prescription only

Venlafaxine XR Teva 75 mg Extended-release capsules The active ingredient and its quantity: Each capsule contains:

Venlafaxine 75 mg (as Hydrochloride)

Venlafaxine XR Teva 150 mg Extended-release capsules
The active ingredient and its quantity:

Fach capsule contains:
Venlafaxine 150 mg (as Hydrochloride)
For information on inactive and allergenic ingredients, see section 2 under "Important information about some of the ingredients in this medicine" and section 6 "Further information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

Antidepressants and anti-anxiety medicines increase the risk of suicidal behavior and thoughts in children, adolescents and young adults up to the age of 25. Upon initiation of treatment with the medicine, patients of all ages, and their relatives, must monitor behavioral changes such as: worsenling of depression, suicidal thoughts, aggressiveness and the like. If such changes occur, refer to a doctor immediately. WHAT IS THE MEDICINE INTENDED FOR?

1. WHAT IS THE MEDICINE INTENDED FOR?

Venlafaxine XR Teva is an antidepressant that belongs to the group of SNRIs (Serotonin Noradrenaline Reuptake Inhibitors) antidepressants. This group of medicines is used to treat depression and for treatment of various anxiety disorders. The mechanism of action of antidepressants is not sufficiently understood; these medicines may affect the increase of serotonin and noradrenaline levels in the brain. Venlafaxine XR Teva is intended for treatment of adults with depression. It is also a treatment for adults with the following anxiety disorders: generalized anxiety and social anxiety. Treating depression and anxiety disorders is very important. If untreated, your condition may not resolve itself and may even become more serious, and thus more difficult to treat in the future. Therapeutic group: herapeutic group: Antidepressants of the SNRIs (Serotonin Noradrenaline Reuptake Inhibitors) group. BEFORE USING THE MEDICINE:

Do not use the medicine if:
 You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine.

- medicine.

 Do not use this medicine concomitantly with medicines used for treating depression or Parkinson's disease belonging to the monoamine oxidase inhibitors class (MAOIs). Taking MAOI-type medicines with Venlafaxine XR Teva may cause severe and life threatening side effects. Wait 14 days from the day of finishing treatment with an MAOI until starting treatment with Venlafaxine XR Teva, and a week after finishing treatment with Venlafaxine XR Teva before starting treatment with an MAOI.

 Decial warnings regarding the use of this medicine: Special warnings regarding the use of this medicine Special warnings regarding the use of this medicine:
 Before beginning treatment with Venlafaxine XR Teva, tell your doctor if:

 you are taking additional medicines that could increase the risk of developing serotonin syndrome when taken together with Venlafaxine XR Teva (see section 2, in the "Drug interactions" subsection).

 you are suffering from eye diseases, such as certain kinds of glaucoma (increased pressure in the eye).

 you are suffering, or have suffered in the past, from hypertension.
- hypertension. you are suffered in the past, from heart diseases or from irregular heart rhythm. you have suffered in the past from seizures. you have suffered from low blood sodium levels (hyponatremia). you have a tendency to develop bruises (hemorrhaging under the skin) or to bleed easily (history of coagulation disorders), or if you are taking medicines that may increase the risk of bleeding, such as warfarin. you have a history of or if someone in your family has
- you have a history of, or if someone in your family has had, mania or bipolar disorder (manic depression). you have a history of aggressive behavior. What you should know before taking Venlafaxine XR Teva:

What you should know before taking Venlafaxine XR 'eva:

Venlafaxine XR Teva may cause a sensation of restlessness or an inability to sit or stand still during the first few weeks of treatment. You should tell the doctor if you suffer from this condition.

Suicidal thoughts and worsening of depression or anxiety:

If you suffer from depression or anxiety, you may have thoughts of harming yourself or committing suicide. In this case, contact a doctor or go to a hospital immediately. These thoughts may intensify when you first start taking antidepressants, since these medicines take time to start working, usually about two weeks, but sometimes longer. It is recommended to tell a relative or a friend that you suffer from depression or anxiety, and ask them to read this leaflet. Ask them, if in their opinion, they think your depression or anxiety is getting worse, or if they are worried about changes in your behavior. Patients and their family members are advised to follow behavioral changes, such as: worsening of depression, suicidal thoughts, aggressiveness and the like. If such changes occur, contact a doctor immediately. Pay particular attention to this recommendation in young patients under the age of 25.

Dry mouth: Dry mouth has been reported in approximately 10% of patients treated with Venlafaxine XR Teva. This

- patients under the age of 25.

 Dry mouth: Dry mouth has been reported in approximately 10% of patients treated with Venlafaxine XR Teva. This may increase the risk of tooth decay. Therefore, you should be particular about dental hygiene.

 Diabetes: If you are diabetic, consult with the doctor about adjusting the dosage of your sugar-reducing medicines. Use by children and adolescents under 18 years of age:
 This medicine is not intended for use in children and adolescents under the age of 18. In children and adolescents under the age of 18 who have taken this medicine, an increase in side effects, such as attempted suicide, suicidal thoughts and hostility (predominantly aggression, oppositional behavior and anger) has been observed.

 Nevertheless, the doctor may prescribe this medicine
- observed.

 Nevertheless, the doctor may prescribe this medicine to patients under 18 years of age when he thinks it is to their benefit. If the doctor prescribed this medicine for you and you are interested in talking to him, refer to the doctor again. In patients under 18 years of age who are taking this medicine, tell the doctor if any of the listed side effects occur or worsen. In addition, there is no information regarding the long-term safety effects regarding growth a wheth and continue development. regarding growth, puberty and cognitive development and behavioral development in this group. Drug interactions:
 If you are taking, or have recently taken, other medicines, including non-prescription medicines or nutritional supplements, tell the doctor or pharmacist before starting treatment with Venlafaxine XR Teva, in order to prevent risks or lack of efficacy that results from drug interactions.

In particular, inform the doctor or pharmacist if you are taking:

taking:

Monoamine oxidase inhibitors (MAOIs) (such as moclobemide) that are used to treat depression or Parkinson's disease - must not be taken concomitantly with Venlafaxine XR Teva. Tell the doctor if you have taken medicines of this type within the last 14 days (see detailed information in section 2, in the "Do not use the medicine if" subsection).

Sentonio syndrome: Serotonin syndrome:

Serotonin syndrome:
Certain medicines may cause serotonin syndrome (rare). This is a syndrome that may be fatal and may include symptoms such as nervousness, hallucinations, loss of balance, fast heartbeat, raised body temperature, rapid changes in blood pressure, diarrhea, loss of consciousness, nausea and vomiting, heightened reflexes (see section 4 "Side effects"). The syndrome may occur more frequently if you are concurrently taking additional medicines that affect the nervous system. In its most severe form, the syndrome can manifest as Neuroleptic Malignant Syndrome (NMS), whose signs and symptoms include a combination of fever, fast heartbeat, sweating, severe muscle stiffness, confusion, and increased muscle enzymes (can be identified by a blood test).
Medicines that may cause this syndrome when taken in combination with Venlafaxine XR Teva include:

• medicines that contain triptans such as medicines for treating migraine;

• other medicines for the treatment of deposicion for

ombination with vehitaristic AH reva include:
medicines that contain triptans such as medicines for
treating migraine;
other medicines for the treatment of depression, for
instance, medicines of the SSRI and SNRI groups,
tricyclic antidepressants or lithium;
medicines containing linezolid (an antibiotic for treatment
of infections);
medicines containing moclobemide, a monoamine
oxidase inhibitor (MAOI) for treatment of depression;
medicines containing sibutramine (for weight loss);
medicines containing tramadol, fentanyl, tapentadol,
pethidine or pentazocine (medicines used to relieve
pain);
medicines containing dextromethorphan (a medicine
used to alleviate coughing);
medicines containing methadone which is used for
treatment of addiction to opiates or severe pain;
preparations containing St. John's Wort (Hypericum
perforatum, a plant extract used for treatment of
depression), such as Remotiv;
preparations containing tryptophan (an amino acid

perforatum, a plant extract used for treatment of depression), such as Remotiv;
preparations containing tryptophan (an amino acid present in foods, in solutions for parenteral nutrition, and in nutritional supplements used for inducing sleep and as an antidepressant);
antipsychotic medicines such as clozapine, olanzapine, quetiapine or ziprasidone, used to treat symptoms such as hearing, seeing or sensing non-existent objects, delusions, unusual suspicions, unclear thoughts, and becoming withdrawn.

medicines containing methylene blue for treating high levels of blood methemoglobin.

Tell the doctor immediately, or proceed to the emergency room at your nearest hospital if you think you are suffering from serotonin syndrome.

Inform the doctor if you are taking medicines that affect heart rhythm. For example: antiarrhythmics, such as: quinidine, amiodarone, sotalol or dofetilide.
antipsychotics such as thioridazine.
antibiotics such as erythromycin or moxifloxacin (to treat a bacterial infection).
antihistamines (to treat allergy).
There may be drug interactions between Venlafaxine XR Teva and additional medicines. It is particularly important to inform your doctor if you are taking:
Ketoconazole (an antifungal),
Haloperidol or risperidone (to treat psychiatric conditions),
Metoprolol (a beta blocker to treat blood pressure and heart diseases).
Report to the doctor about any additional medicine that you are taking.

Huse of the medicine and food:
Take Venlafaxine XR Teva with food (see section 3 "How should you use the medicine?"). Use of the medicine and alcohol consumption:

<u>Do not drink wines</u> or alcoholic beverages while being treated with the medicine.

<u>uo not arink wines</u> or alcoholic beverages while being treated with the medicine. **IP Pregnancy and breastfeeding:**Inform the doctor if you are pregnant, or if you want to become pregnant. Venlafaxine XR Teva can only be used after a consultation with your doctor regarding the potential risks to the fetus.

Inform your doctor and midwife regarding use of Venlafaxine XR Teva during pregnancy. Venlafaxine XR Teva may increase the risk for persistent pulmonary hypertension of the newborn (PPHN), a dangerous condition in which the newborn turns blue and breathes quickly. These symptoms usually begin during the first 24 hours after birth. If you notice this condition, consult the midwife or doctor immediately.

Another sign that may appear in the newborn whose mother took Venlafaxine XR Teva during pregnancy is that the newborn may not feed properly. In such a case, consult the doctor.

Venlafaxine XR Teva passes into breast milk and therefore, there is a risk that the medicine will be passed on to the infant. Hence, consult with the doctor, in order to decide whether you should stop breastfeeding or stop taking this medicine. **IP Driving and operating machinery:**

- Report to the doctor about any additional medicine that you are taking.

3. HOW SHOULD YOU USE THE MEDICINE? Always use this preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and instructions for use of the preparation.

this medicine.

B Driving and operating machinery:
Use of this medicine may impair alertness; therefore, exercise caution when driving a car, operating dangerous machinery and when engaging in any activity which requires alertness. Do not engage in such activities until you know how the medicine affects you. you know how the medicine affects you.

Ill Important information about some of the ingredients in this medicine:

Venlafaxine XR Teva contains sucrose. If your doctor told you have an intolerance to a certain type of sugar, consult with the doctor before taking this medicine.

Each Venlafaxine XR Teva 75 mg capsule contains 45.88 mg sucrose.

Each Venlafaxine XR Teva 150 mg capsule contains 91.77 mg sucrose.

The medicine contains a vellow color Sunset FCF (Sunset)

The medicine contains a yellow color Sunset FCF (Sunset yellow FCF), which may cause allergic reactions.

Crushing/halving/chewing:

Do not open, crush, chew or dissolve the capsules.

The optimal effect of SNRI medicines may only begin manifesting after a few weeks of treatment; this period varies from patient to patient. If after a few weeks there is no improvement in your condition, refer to a doctor.

no improvement in your condition, reter to a doctor.

Tests and follow-up
Venlafaxine XR Teva may cause undesirable effects
that you will not be aware of, such as, increased blood
pressure or heart rhythm disturbances, slight changes in
liver enzyme levels, blood sodium or cholesterol levels,
and in rare cases, also a decrease in platelets (a tendency
for bruising and bleeding). Therefore, during the treatment
period, you may be referred for medical tests for follow-up
purposes, particularly if you have been taking Venlafaxine
XR Teva for an extended period.

If you accidentally took a higher dosage, immediately

XR Teva for an extended period.

If you accidentally took a higher dosage, immediately consult with the doctor or pharmacist. If you took an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you. Do not induce vomiting unless explicitly instructed to do so by the doctor!

Signs of overdose may include rapid heartbeat, changes in the level of alertness (from sleepiness to coma), blurred vision, convulsions and vomiting.

If you forgot to take this medicine at the required time,

If you forgot to take this medicine at the required time, take the dose as soon as you remember. However, if it is time for the next dose, skip the missed dose. Never take two doses together!

Adhere to the treatment regimen recommended by the doctor.

If you stop taking the medicine:

Do not stop treatment with the medicine or reduce the dosage without consulting a doctor, even if you are feeling better. If your doctor thinks you should stop treatment, he or she may advise you to reduce the dosage gradually before stopping treatment.

Side effects may occur when stopping treatment, especially when the treatment is stopped suddenly or when the dosage is reduced too rapidly. Some patients may experience effects such as tiredness, dizziness, headache, insomnia, nightmares, dry mouth, loss of appetite, nausea, diarrhea, nervousness, restlessness, confusion, ringing in the ears, tingling or, in rare instances, electric shock sensations, weakness, sweating, seizures, flu-like symptoms.

Your doctor will advise you on how to reduce the dosage gradually. If you experience one or more of these or other worrisome symptoms, consult your doctor.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult you have further questions regarding use of the medicine, consult you have further questions regarding use of the medicine, consult you have further questions regarding use of the medicine, consult you have further questions regarding use of the medicine, consult the doctor or charmacist

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4. SIDE EFFECTS: 4. SIJLE EFFECTS:
As with any medicine, use of Venlafaxine XR Teva may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.
Discontinue use and immediately refer to a doctor or proceed to an emergency room if one or more of the following side effects occur:

Swelling of the face, tongue, mouth, throat, hands, or feet and/or itchy and raised rash, difficulty swallowing and breathing.

Uncommon side effects:

Side effects of unknown frequency:
Chest tightness, wheezing.
Severe skin rash, itching, or hives (elevated, red or colorless skin lesions that usually itch).

olorless skin lesions that usually itch).

Signs and symptoms of serotonin syndrome which may include: restlessness, hallucinations, lack of coordination, fast heartbeat, increased body temperature, rapid changes in blood pressure, overactive reflexes, diarrhea, 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 high fever, fast heartbeat, sweating, severe muscle stiffness, confusion, increased muscle enzymes (determined by a blood test).

Signs of infection, such as high fever, chills, tremor, headaches, sweating and flu-like symptoms. These symptoms may be caused by a blood system disturbance, which leads to increased risk of infections. Severe rash which may cause severe blistering and peeling of the skin.

Unexplained muscle pains, tenderness or weakness. These may be signs of rhabdomyolysis. Refer to a doctor as soon as possible if you experience one of the following effects:

• Coughing, wheezing, shortness of breath and a high temperature;

- Black stools or blood in stools;
 Yellow skin or eyes, itchiness or dark urine (may indicate hepatitis); nepatitis);
 Heart problems (such as rapid or irregular heartbeat, increased blood pressure);
 Eye problems (blurred vision, dilated pupils);
 Nerve problems (dizziness, pins and needles, movement disorder, convulsions);
 Psychiatric problems, such as hyperactivity and euphoria (overexcitement);
 Withdrawal symptoms (see section 3, under "How Withdrawal symptoms (see section 3, under "How
 - (overexcitating), Withdrawal symptoms (see section 3, under "How should you use the medicine?" and section 3, under "If you stop taking the medicine"); Prolonged bleeding (bleeding lasts longer than usual following cuts or injuries).

tollowing cuts or injuries).

If you notice small white balls or granules in your stools during treatment with Venlafaxine XR Teva, there is no need to worry. Each Venlafaxine XR Teva capsule contains spheroids (small white balls) that contain the active ingredient, venlafaxine. The spheroids in the capsule are released in your stomach and the active ingredient in them is slowly released during passage through the stomach and intestines. The shell of the spheroids does not dissolve and is passed out in the stool. That is to say, the required dose is absorbed despite the appearance of spheroids in the stool. Additional side effects that may occur: Additional side effects that may occur: Very common side effects

Dizziness, headaches

Nausea, dry mouth Common side effects Decreased appetite Confusion, feeling of detachment from yourself, inability to reach orgasm, decreased libido, nervousness, insomnia, abnormal dreams Insomnia, abnormal dreams
Drowsiness, tremor, pins and needles, increased muscle
tension (tonus), visual disturbances such as blurred
vision, dilated pupils, inability of the eye to automatically
change focus from distant objects to nearby objects
Ringing in the ears (tinnitus)
Palpitations
Increase in blood pressure, flushing
Yawning

Increased cholesterol levels Uncommon side effects Hallucinations, feeling of detachment from reality, restlessness, orgasm disorders (in women), lack of emotion, feeling of over-excitedness, grinding of teeth Restlessness, involuntary muscle movements, fainting, coordination and balance disorders, altered taste sensation of detachment from reality, disorders (in women), lack of

Yawning
Vomiting, constipation, diarrhea
Increased frequency of urination, difficulties in passing
urine
Menstrual changes (in women), such as increased
bleeding or increased irregular bleeding, ejaculation
or orgasm problem (in men), erectile disorders
(impotence)
Weakness fatigue chills

Yawning

Weakness, fatigue, chills

Shortness of breath

muscles

Vertigo

or internal bleeding)
Generalized swelling of the skin, particularly the face, mouth, tongue, throat or hands and feet and/or raised itchy rash, tendency to bruise, sensitivity upon exposure to the sun, rash, abnormal hair loss
Rapid heartbeat, dizziness (mainly when moving from a lying to standing position)
Weight gain, weight loss
Inability to pass urine

Rare side effects
Convulsions
Inability to control urination
Hyperactivity, racing thoughts and decreased need for sleep (mania)

Side effects of unknown frequency:
Prolonged bleeding time, which may indicate reduced platelet levels (may lead to bruises and bleeding), blood system disorders (may increase the risk of infection)
Accumulation of fluids in the body due to excessive secretion of ADH hormone
Decrease in blood sodium levels
Suited the other care of which a behavior (during and one).

Bloody vomit or black or bloody stools (may be a sign of internal bleeding)

Decrease in blood sodium levels
Suicidal thoughts and suicidal behavior (during and even
after stopping treatment with Venlafaxine XR Teva – see
section 2, in the "Special warnings regarding the use of
this medicine" subsection)
Disorientation and confusion sometimes accompanied
by hallucinations (delirium); aggressiveness
Stiffness, spasms and involuntary movements of the
muscles

Severe eye pain, decreased or blurred vision

increase in white blood ceils (pulmonary eosinophilla)

Severe abdominal or back pain, suggesting a serious
problem in the intestines, liver or pancreas

Itching, yellow skin or eyes, dark urine, flu-like symptoms,
which may indicate inflammation of the liver (hepatitis);
slight changes in blood levels of liver enzymes

Itching and mild rash

Abnormal breast milk production

If these effects are bothersome or last for more than a few
days, refer to a doctor.

days, refer to a doctor.
If a side effect occurs, if any of the side effects worsen, or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor.

Vertigo
Decrease in blood pressure; abnormal, rapid or irregular heartbeat, which could lead to fainting; unexpected bleeding (such as bleeding gums, blood in vomit or urine, or unexpected appearance of bruises or damage to blood vessels)
Symptoms of pneumonia, such as: coughing, wheezing, difficulties breathing and a high temperature, with an increase in white blood cells (pulmonary eosinophilla). Severe abdominal or back pair, suggesting a serious

Reporting side effects
Side effects can be reported to the Ministry of Health
by clicking on the link "Report Side Effects of Drug
Treatment" found on the Ministry of Health homepage
(www.health.gov.il) that directs you to the online form for
reporting side effects, or by entering the link:
https://forms.gov.il/globaldata/getsequence/getsequence.
aspx?formType=AdversEffectMedic@moh.gov.il

 NOW SHOULD THE MEDICINE BE STORED?
 Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of reach and sight of children and/or infrants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

 De not use the medicine after the avoire data (exp. data). Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month. Store in a dry place, below 25°C.

6. FURTHER INFORMATION

6. FURTHER INFORMATION
In addition to the active ingredient, the medicine also contains the following inactive ingredients:
Venlafaxine XR Teva 75 mg
Sugar spheres, ethylcellulose, povidone, polyethylene glycol, dibutyl sebacate, talc, gelatin, titanium dioxide, sunset yellow FCF-FD&C yellow 6 (E110), D&C yellow 10, printing ink.
Venlafaxine XR Teva 150 mg
Sugar spheres, ethylcellulose, povidone, polyethylene Sugar spheres, ethylcellulose, povidone, polyethylene glycol, dibutyl sebacate, talc, gelatin, titanium dioxide, sunset yellow FCF-FD&C yellow 6 (E110), printing ink. What the medicine looks like and the contents of the

What the hields like and the contents of the package:

Venlafaxine XR Teva 75 mg is a light yellow, opaque capsule, filled with white to off-white granules, packaged in trays (blister).

Venlafaxine XR Teva 150 mg is a light orange opaque capsule, filled with white to off-white granules, packaged in trays (blister).

Venlafaxine XR Teva 75 mg and Venlafaxine XR Teva 150 mg are supplied in tray (blister) containing 28 or 30 capsules.

Not all package sizes may be marketed.

Address:

Not all package sizes may be marketed.

Name of Manufacturer and License Holder and its

Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petach

This leaflet was checked and approved by the Ministry of Health in August 2015 and was updated in April 2018 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Venlafaxine XR Teva 75 mg: 131.53.30975
Venlafaxine XR Teva 150 mg: 131.54.30976

VENL CAPS PL SH 300518 322K005481118

The dosage and treatment regimen will be determined by the doctor only. The usual dosage to treat depression, generalized anxiety and social anxiety is generally: 75 mg per day. The doctor may gradually raise the dosage, if necessary. The maximal dosage to treat depression is 375 mg per day. The maximal dosage for treatment of generalized or social anxiety is 225 mg per day.

Do not exceed the recommended dose.

Swallow the medicine with a little water. Swallow the capsules whole.

Take the medicine with a meal, in the morning or evening, at around the same time every day. If you have a liver or kidney function problem, report it to the doctor, since the dosage of the medicine may have to be changed. Do not stop taking the medicine unless explicitly instructed to do so by your doctor.

Crushing/halving/chewing: