

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed according to a physician's prescription only

WELLBUTRIN XR 150 mg modified release tablets

Each tablet contains:

bupropion hydrochloride 150 mg

WELLBUTRIN XR 300 mg modified release tablets

Each tablet contains:

bupropion hydrochloride 300 mg

For the list of the inactive and allergenic ingredients in the medicine, see section 6 – “Additional information”.

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

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

Wellbutrin XR is not intended for treatment of children under 18 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

Wellbutrin XR is a medicine intended for the treatment of depression. It is thought to interact with chemicals in the brain called *noradrenaline and dopamine*.

Therapeutic group:

Selective noradrenaline-dopamine reuptake inhibitor.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to bupropion or to any of the additional ingredients contained in this medicine (listed in section 6).

- **You are taking any other medicines that contain bupropion**
- **You have been diagnosed with epilepsy or have a history of seizures**
- **You have or used to have an eating disorder** (for example, bulimia or anorexia nervosa)
- **You have a brain tumor**
- **You are usually a heavy drinker** and have just stopped, or are about to stop, drinking
- **You have severe liver problems**
- **You recently stopped taking sedatives**, or you are going to stop them, while taking Wellbutrin XR
- **You are taking or have taken other medicines for depression** or for Parkinson's disease called *monoamine oxidase inhibitors* (MAOIs) in the last 14 days.

If one of these apply to you, talk to your physician straight away, without taking Wellbutrin XR.

Special warnings regarding use of the medicine

Talk to your physician or pharmacist before using Wellbutrin XR.

Children and adolescents

Wellbutrin XR is not intended to treat children under 18 years of age.

There is an increased risk of suicidal behavior and thoughts when children under 18 years of age are treated with antidepressants.

Adults

Your physician needs to know before you take Wellbutrin XR if:

- **you regularly drink a lot of alcohol**
- **you have diabetes** for which you use insulin or tablets
- **you have had a serious head injury or a history of head trauma**

Wellbutrin XR has been shown to cause fits (seizures) in about 1 in 1,000 people. This side effect is more likely to occur in people from the groups mentioned above. If you have a fit during treatment you should stop taking Wellbutrin XR. **Do not take any more and refer to your physician.**

- **you have a bipolar disorder** (extreme mood swings), as Wellbutrin XR could bring on an episode of this illness
- **If you are taking other medicines for depression**, the use of these medicines together with Wellbutrin XR can lead to serotonin syndrome, a potentially life-threatening condition (see “Drug interactions” in this section)
- **you have liver or kidney problems**, you may be more likely to get side effects.

If any of the above-mentioned applies to you, talk to your physician again before taking Wellbutrin XR. He may want to pay special attention to your care, or recommend another treatment.

Suicidal thoughts and worsening of your depression

If you are depressed, you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting to take 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 of suicidal behavior in adults under the age of 25 with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your physician or go to a 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 can ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behavior.

Drug interactions

If you are taking, or have taken other medicines for depression or for Parkinson’s disease called *monoamine oxidase inhibitors* (MAOIs) in the last 14 days, **tell your physician without taking Wellbutrin XR** (see also “Do not use the medicine if” in section 2).

If you are taking, have recently taken or might take other medicines, including non-prescription medicines and nutritional supplements, tell the physician or the pharmacist. They may alter the dose of Wellbutrin XR, or suggest a change in your other medicines.

Some medicines do not mix with Wellbutrin XR. Some of them may increase the chance of fits or seizures. Other medicines may increase the risk of other side effects. Some examples are listed below, but it is not a complete list.

There may be a higher than usual chance of seizures if:

- **you take other medicines for depression or other mental illnesses**
- **you take theophylline** for asthma or lung disease
- **you take tramadol**, a strong painkiller
- **you have taken sedatives**, or if you are going to stop them while you are taking Wellbutrin XR (see also “Do not use the medicine if” in section 2)
- **you take medicines against malaria** (such as mefloquine or chloroquine)
- **you take stimulants or other medicines to control your weight or appetite**
- **you take steroids (by mouth or injection)**
- **you take antibiotics called quinolones**
- **you take some types of anti-histamines that can cause sleepiness**
- **you take medicines for diabetes.**

If any of these apply to you, talk to your physician straight away, before taking Wellbutrin XR. Your physician will consider the benefits and risks to you of taking Wellbutrin XR.

There may be a higher than usual chance of other side effects if:

- **you take other medicines for depression** (such as amitriptyline, fluoxetine, paroxetine, citalopram, escitalopram, venlafaxine, dosulepin, desipramine or imipramine) or other mental illness (such as clozapine, risperidone, thioridazine or olanzapine).

Wellbutrin XR may interact with some medicines used for treatment of depression and you may experience mental status changes (e.g., agitation, hallucinations, coma), and other effects, such as body temperature above

38°C, increase in heart rate, unstable blood pressure, and exaggeration of reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhoea).

- **you take medicines for Parkinson's disease** (levodopa, amantadine or orphenadrine)
- **you take medicines that affect your body's ability to break down Wellbutrin XR** (carbamazepine, phenytoin, valproate)
- **you take certain medicines used to treat cancer** (such as cyclophosphamide, ifosfamide)
- **you take clopidogrel, mainly used to prevent stroke**
- **you take certain beta blockers** (such as metoprolol)
- **you take certain medicines for irregular heart rhythm** (propafenone or flecainide)
- **you use nicotine patches to help you stop smoking.**

If any of these apply to you, talk to your physician straight away, before taking Wellbutrin XR.

Wellbutrin XR may be less effective

- **If you take ritonavir or efavirenz, medicines to treat HIV infection.**

If this applies to you, tell your physician. Your physician will check how effective Wellbutrin XR is for you. It may be necessary to increase your dose or change to another treatment for your depression. **Do not increase** your Wellbutrin XR dose without consulting with your physician, as this may increase the risk of you having side effects, including seizures.

Wellbutrin XR may decrease the effectiveness of other medicines

- **If you take tamoxifen which is used to treat breast cancer.**

If this applies to you, tell your physician. It may be necessary to change to another treatment for your depression.

- **If you take digoxin for your heart.**

If this applies to you, tell your physician. Your physician may consider adjusting the dose of digoxin.

Use of the medicine and consumption of alcohol

Alcohol can affect the way Wellbutrin XR works and when they are being taken together, can rarely affect your nerves or your mental state. Some people find they are more sensitive to alcohol when taking Wellbutrin XR. Your physician may suggest that you do not drink alcohol (beer, wine or spirits) while taking Wellbutrin XR, or that you try to drink very little. However, if you currently drink a lot, do not stop suddenly: it may put you at risk of having seizures.

Talk to the physician about drinking alcohol before you start taking Wellbutrin XR.

Effect on urine tests

Wellbutrin XR may interfere with some urine tests to detect other drugs. If you need to undergo a urine test, tell your physician or hospital that you are taking Wellbutrin XR.

Pregnancy and breast-feeding

Do not take Wellbutrin XR if you are pregnant, think you may be pregnant or are planning to become pregnant, unless your physician recommends it. Consult your pharmacist or physician before taking this medicine. Some studies, though not all, have reported an increase in the risk of birth defects, particularly heart defects, in babies whose mothers were taking Wellbutrin XR. It is not known if these are due to the use of Wellbutrin XR.

The ingredients of Wellbutrin XR can pass into breast milk. Consult with your physician or pharmacist before taking Wellbutrin XR.

Driving and using machines

If Wellbutrin XR makes you dizzy or if you feel you are about to faint, do not drive or operate any tools or machines.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions. Check with the physician or pharmacist if you are uncertain about the preparation dosage and treatment regimen.

It may take a while before you start to feel better. It takes time for the medicine to have its full effect, sometimes weeks or months. When you do start feeling better, your physician may advise you to keep taking Wellbutrin XR to prevent recurrence of the depression.

The dosage and treatment regimen will be determined by the physician only.

The recommended dosage for adults only is **one** 150 mg tablet, once daily.

Your physician may increase your dose to 300 mg once daily if your depression does not improve after several weeks.

Take your dose of Wellbutrin XR tablets in the morning. Do not take Wellbutrin XR more than once each day.

Do not exceed the recommended dose.

The tablet is covered by a shell that slowly releases the medicine inside your body. You may notice something in your stool that looks like a tablet. This is the empty shell passing from your body.

Swallow the tablets whole. Do not chew them, crush them or split them — if you do, there is a danger you will take an overdose, because the medicine will be released into your body too quickly. This will make you more likely to have side effects, including fits (seizures).

Some people will continue to take one 150 mg tablet every day for their whole period of treatment. Your physician may have prescribed this if you have liver or kidney problems.

How long to take the medicine

Only you and your physician can decide how long you should take Wellbutrin XR. It may take weeks or months of treatment for you to notice any improvement. Discuss your symptoms with your physician regularly to decide how long you will need to take it. When you do start feeling better, your physician may recommend you to keep taking Wellbutrin XR to prevent recurrence of the depression.

The bottle is closed with a child-resistant cap

Opening instructions: to remove the cap, press down, while simultaneously twisting to the left (turning counterclockwise).

Closing instructions: place cap on top of the bottle's open end and twist to the right (turning clockwise) until it locks.

If you accidentally have taken a higher dosage

If you take too many tablets, you may increase the risk of fits or seizures.

If you have taken an overdose or if a child has accidentally swallowed the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine

If you forget to take this medicine at the designated time, **do not take a double dose.**

Take the next dose at the usual time and consult a physician.

Adhere to the treatment regimen recommended by your physician.

If you stop taking the medicine

Even if there is an improvement in your health, **do not** stop taking Wellbutrin XR or reduce the dose without consulting the physician before stopping.

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

If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Wellbutrin XR may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Serious side effects

Fits or seizures

Approximately 1 in every 1,000 people taking Wellbutrin XR is at risk of a fit (a seizure or convulsion). The chance of this happening is higher if you take too much Wellbutrin XR, if you take certain medicines, or if you are at higher than usual risk of fits. If you are concerned, talk to your physician.

If you have a fit, tell your physician after you have recovered. Do not take any more tablets.

Allergic reactions

Some people may get allergic reactions to Wellbutrin XR. These include:

- Red skin or rash (nettle-like rash), blisters or itchy lumps (hives) on the skin. Some skin rashes may require hospital treatment, especially if you also suffer from sore mouth or eyes.
- Unusual wheezing or difficulty in breathing
- Swollen eyelids, lips or tongue
- Muscle or joint pain
- Collapse or loss of consciousness.

If you have any signs of an allergic reaction contact a physician at once. Do not take any more tablets.

Allergic reactions may last a long time. If your physician prescribed something to help with allergy symptoms, make sure you finish the treatment.

Lupus skin rash or worsening of lupus symptoms

Unknown frequency – frequency cannot be estimated from the available data in people taking Wellbutrin XR.

Lupus is an immune system disorder affecting the skin and other organs.

→ **If you experience lupus flares, skin rash or lesions (particularly on sun-exposed areas) while taking Wellbutrin XR, contact your physician straight away, as it might be necessary to stop the treatment.**

Acute Generalised Exanthematous Pustulosis (AGEP)

Not known - frequency cannot be estimated from the available data in people taking Wellbutrin XR.

Symptoms of AGEP include rash with pus filled pimples/blisters.

→ **If you have a rash that has pus filled pimples/blisters, contact your doctor straight away as it might be necessary to stop the treatment.**

Additional side effects

Very common side effects

These may affect **more than 1 in 10** people:

- Difficulty in sleeping. Make sure you take Wellbutrin XR in the morning
- Headache
- Dry mouth
- Feeling sick, vomiting.

Common side effects

These may affect **up to 1 in 10** people:

- Fever, dizziness, itching, sweating and skin rash (sometimes due to an allergic reaction)
- Tremor, weakness, tiredness, chest pain
- Feeling anxious or agitated
- Pain or other abdominal disturbances (constipation), changes in the taste of food, loss of appetite (anorexia)
- Increase in blood pressure, sometimes severe, flushing
- Ringing in the ears, visual disturbances.

Uncommon side effects

These may affect **up to 1 in 100** people:

- Feeling depressed (see also section 2 “Special warnings regarding the use of the medicine”, under “Suicidal thoughts and worsening of your depression”)
- Feeling confused
- Difficulty concentrating

- Increased heart rate
- Weight loss.

Rare side effects

These may affect **up to 1 in 1,000** people:

- Seizures.

Very rare side effects

These may affect **up to 1 in 10,000** people:

- Palpitations, fainting
- Twitching, muscle stiffness, uncontrolled movements, problems with walking or coordination
- Feeling restless, irritable, hostile, aggressive, strange dreams, tingling sensation or numbness, loss of memory
- Yellowing of the skin or the whites of your eyes (*jaundice*) which may be caused by raised liver enzymes, hepatitis
- Severe allergic reactions; rash together with joint and muscle pain
- Changes in blood sugar levels
- Urinating more or less than usual
- Urinary incontinence (involuntary urination, leakage of urine)
- Severe skin rashes that may occur in the mouth and other parts of the body and can be life-threatening
- Worsening of psoriasis (thickened patches of red skin)
- A sense of detachment from reality or strangeness (*depersonalization*); seeing or hearing things that are not there (*hallucinations*); sensing or believing things that are not true (*delusions*); severe suspiciousness (*paranoia*).

Side effects of unknown frequency

Other side effects have occurred in a small number of people but their exact frequency is unknown:

- Thoughts of self-harm or suicidal thoughts while taking Wellbutrin XR or soon after stopping treatment (see section 2, “Before using the medicine”). If you have such thoughts, **contact your physician or go to a hospital straight away.**
- Loss of contact with reality and inability to think or judge clearly (*psychosis*); other symptoms may include hallucinations and/or delusions.
- Stuttering.
- Reduced numbers of red blood cells (anemia), reduced numbers of white blood cells (leucopenia) and reduced numbers of platelets (thrombocytopenia).
- Reduced blood sodium level (hyponatremia).
- Change in mental status (e.g., agitation, hallucinations, coma), and other effects, such as body temperature above 38°C, increase in heart rate, unstable blood pressure and exaggeration of reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhoea), while taking Wellbutrin XR together with medicines used for treatment of depression (such as paroxetine, citalopram, escitalopram, fluoxetine and venlafaxine).

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.

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.it) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.it/>

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.

- 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 below 25°C. Store in the original package in order to protect from moisture and light.
- For use up to 30 days after opening.
- The bottle contains a small sealed canister containing charcoal and silica gel to keep the tablets dry. Keep the canister in the bottle. Do not swallow it.
- Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredients, the medicine also contains:
The tablet contains:
Polyvinyl alcohol, glyceryl dibehenate.
The tablet coating contains:
Ethylcellulose, povidone K-90, methacrylic acid ethyl acrylate copolymer dispersion (Eudragit L30 D-55), macrogol 1450, silicon dioxide, triethyl citrate.
Printing ink:
Shellac glaze, iron oxide black (E172), ammonium hydroxide.
- What the medicine looks like and the contents of the package:
Wellbutrin XR 150 mg tablets are creamy white to pale yellow round tablets imprinted with "GS5FV" in black ink on one side, and the other side is plain. They are available in white polyethylene bottles containing 7, 30 or 90 (3X30) tablets. The bottle is closed with a child-resistant cap.
Wellbutrin XR 300 mg tablets are creamy white to pale yellow round tablets imprinted with "GS5YZ" in black ink on one side, and the other side is plain. They are available in white polyethylene bottles containing 7, 30 or 90 (3X30) tablets. The bottle is closed with a child-resistant cap.
Not all package sizes may be marketed.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.

- Manufacturer: Bausch Health Companies Inc., Manitoba, Canada.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Wellbutrin XR 150 mg: 140-05-31653
Wellbutrin XR 300 mg: 140-06-31654

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