

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986

This medicine is dispensed with a doctor's prescription only

Bupropion Hydrochloride 150 mg XR tablets

Bupropion Hydrochloride 300 mg XR tablets

Active ingredient

Each Bupropion Hydrochloride 150 mg XR tablet contains:
bupropion hydrochloride 150 mg

Each Bupropion Hydrochloride 300 mg XR tablet contains:
bupropion hydrochloride 300 mg

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

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or 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 to yours.

Bupropion Hydrochloride XR tablets are not intended for treatment of children under 18 years of age.

Antidepressants and anti-anxiety medicines increase the risk of suicidal thoughts and behavior in children, adolescents, and young adults up to the age of 25. Upon starting treatment with the medicine, patients of all ages and their relatives must monitor behavioral changes, such as worsening depression, suicidal thoughts, aggression, etc. If any of such changes occur, contact your doctor immediately.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Bupropion Hydrochloride XR tablets are indicated for the treatment of major depressive episodes. Following satisfactory response, continuation of treatment with Bupropion Hydrochloride XR tablets is effective in preventing relapse.

Therapeutic group: Antidepressants.

Selective noradrenaline-dopamine reuptake inhibitor.

2. BEFORE USING THE MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to bupropion or to any of the other ingredients in this medicine (see section 6).
- **You are taking 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 Bupropion Hydrochloride XR tablets.

- **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 any of these applies to you, talk to your doctor straight away, without taking Bupropion Hydrochloride XR tablets.

Special warnings about using this medicine

Talk to your doctor or pharmacist before using Bupropion Hydrochloride XR tablets.

Brugada syndrome

If you have a condition called Brugada syndrome (a rare hereditary syndrome that affects the heart rhythm) or if cardiac arrest or sudden death occurred in your family.

Your doctor needs to know before you take Bupropion Hydrochloride XR tablets 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.**
Bupropion Hydrochloride XR tablets have been shown to cause fits (seizures) in about 1 in 1,000 users. 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 Bupropion Hydrochloride XR tablets. **Do not take any more and refer to your doctor.**
- **you have a bipolar disorder** (extreme mood swings), as Bupropion Hydrochloride XR tablets could bring on an episode of this illness.
- **you are taking other medicines for depression;** the use of these medicines together with Bupropion Hydrochloride XR tablets 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 doctor again before taking Bupropion Hydrochloride XR tablets. He may want to pay special attention to your care, or recommend another treatment.

Suicidal thoughts and worsening of depression

If you are depressed, you can sometimes have thoughts of harming or killing yourself. These thoughts 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 experience 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 doctor 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.

Children and adolescents

Bupropion Hydrochloride XR tablets are 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.

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 doctor without taking Bupropion Hydrochloride XR tablets** (see also "Do not use this medicine if" in this section).

If you are taking, have recently taken or might take other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. The doctor may alter the dose of Bupropion Hydrochloride XR tablets, or suggest a change in your other medicines.

Some medicines cannot be combined with Bupropion Hydrochloride XR tablets. 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 Bupropion Hydrochloride XR tablets (see also “Do not use this medicine if” in this section)
- **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 may cause sleepiness**
- **you take medicines for diabetes.**

If any of these applies to you, talk to your doctor straight away, before taking Bupropion Hydrochloride XR tablets. Your doctor will consider the benefits and risks to you associated with taking Bupropion Hydrochloride XR tablets.

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 illnesses (such as clozapine, risperidone, thioridazine or olanzapine).
Bupropion Hydrochloride XR tablets 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 exaggerated reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea).
- **you take medicines for Parkinson’s disease** (levodopa, amantadine or orphenadrine)
- **you take medicines that affect your body’s ability to break down bupropion** (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 applies to you, talk to your doctor straight away, before taking Bupropion Hydrochloride XR tablets.

Bupropion Hydrochloride XR tablets may be less effective

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

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

Bupropion Hydrochloride XR tablets 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 doctor. 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 doctor. Your doctor may consider adjusting the dose of digoxin.

Using this medicine and food

The medicine can be taken with or without food.

Using this medicine and alcohol consumption

Alcohol can affect the way Bupropion Hydrochloride XR tablets work 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 bupropion. Your doctor may suggest that you do not drink alcohol (beer, wine or spirits) while taking Bupropion Hydrochloride XR tablets, or that you try to drink very little. However, if you currently drink a lot, do not stop suddenly; it may increase the risk of having seizures.

Talk to the doctor about drinking alcohol before you start taking Bupropion Hydrochloride XR tablets.

Effect on urine tests

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

Pregnancy and breastfeeding

Pregnancy

Do not take Bupropion Hydrochloride XR tablets if you are pregnant, think you may be pregnant or are planning to become pregnant, unless your doctor recommends it. Consult your doctor or pharmacist 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 bupropion. It is not known if these are due to the use of bupropion.

Breastfeeding

The ingredients of Bupropion Hydrochloride XR tablets can pass into breast milk. Consult with your doctor or pharmacist before taking Bupropion Hydrochloride XR tablets.

Driving and using machines

If Bupropion Hydrochloride XR tablets make you dizzy or feel you are about to faint, do not drive or operate any tools or machines.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

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

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

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

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

Take your dose of Bupropion Hydrochloride XR tablets in the morning. Do not take bupropion more than once a 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, crush or split them — if you do, there is a danger that 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).

The tablets may have an odor. This is normal.

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

How long to take the medicine

Only you and your doctor can decide how long you should take Bupropion Hydrochloride XR tablets. It may take weeks or months of treatment for you to notice any improvement. Discuss your symptoms with your doctor regularly to decide how long you will need to take it. When you do start feeling better, your doctor may recommend you to keep taking Bupropion Hydrochloride XR tablets 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 have accidentally taken a higher dose

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 some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine

If you forget to take this medicine at the scheduled time, wait and take the next tablet at the usual time.

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

Adhere to the treatment as recommended by your doctor.

If you stop taking this medicine

Even if your health improves, **do not** stop taking Bupropion Hydrochloride XR tablets or reduce the dose without consulting your doctor before stopping.

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

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

Like with all medicines, using Bupropion Hydrochloride XR tablets may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Serious side effects

Fits or seizures

Approximately 1 in every 1,000 people taking Bupropion Hydrochloride XR tablets is at risk of a fit (a seizure or convulsion). The chance of this happening is higher if you take too much

Bupropion Hydrochloride XR tablets, if you take certain medicines, or if you are at higher than usual risk of fits. If you are concerned, talk to your doctor.

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

Allergic reactions

Some people may experience allergic reactions to Bupropion Hydrochloride XR tablets. 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 doctor at once. Do not take any more tablets.

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

Lupus skin rash or worsening of lupus symptoms

Unknown frequency – frequency cannot be estimated from the available data in people taking Bupropion Hydrochloride XR tablets.

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 Bupropion Hydrochloride XR tablets, contact your doctor straight away, as it might be necessary to stop the treatment.**

Acute Generalised Exanthematous Pustulosis (AGEP)

Unknown frequency – frequency cannot be estimated from the available data in people taking Bupropion Hydrochloride XR tablets.

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 – may affect **more than 1 in 10** users:

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

Common side effects – may affect **up to 1 in 10** users:

- 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 – may affect **up to 1 in 100** users:

- Feeling depressed (see also section 2 “Special warnings about using this medicine”, under “Suicidal thoughts and worsening of depression”)
- Feeling confused
- Difficulty concentrating
- Increased heart rate
- Weight loss.

Rare side effects – may affect **up to 1 in 1,000** users:

- Seizures.

Very rare side effects – may affect **up to 1 in 10,000** users:

- 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)
- Unusual hair loss or thinning (alopecia)
- 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 (the frequency of these effects has not been established yet)

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 Bupropion Hydrochloride XR tablets or soon after stopping treatment (see section 2, “Before using this medicine”). If you have such thoughts, **contact your doctor 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.
- Sudden sensation of severe fear (panic attack)
- 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 exaggerated reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea), while taking Bupropion Hydrochloride XR tablets together with medicines used for treatment of depression (such as paroxetine, citalopram, escitalopram, fluoxetine and venlafaxine).

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link ‘Reporting Side Effects of Drug Treatment’ on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

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

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store at 25°C.
- For use up to 30 days after opening.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, this medicine also contains:

Povidone K-90, ethyl cellulose, povidone K-30, L (+) – tartaric acid, glyceryl distearate, hydroxypropyl cellulose, methacrylic acid copolymer, colloidal silicone dioxide, magnesium stearate

Printing ink:

Opacode black S-1-17823

What the medicine looks like and contents of the pack:

Bupropion Hydrochloride 150 mg XR tablets are white to creamy round film-coated tablets imprinted with “ST 150” in black ink on one side, and the other side is plain. They are available in white polyethylene bottles containing 30 tablets. The bottle is closed with a child-resistant cap.

Bupropion Hydrochloride 300 mg XR tablets are white to creamy round film-coated tablets imprinted with “ST 300” in black ink on one side, and the other side is plain. They are available in white polyethylene bottles containing 30 tablets. The bottle is closed with a child-resistant cap.

Registration holder’s name and address: Ofek Pharma Ltd., 22 Snir St. Bnei Dror, 4581500

Manufacturer’s name and address:

Hangzhou Minsheng Binjiang Pharmaceuticals Co. Ltd.,
658 Bin’an Road Binjiang District, Hangzhou, Zhejiang 310051, China.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Bupropion Hydrochloride 150 mg XR tablets: 171-57-37133-99

Bupropion Hydrochloride 300 mg XR tablets: 171-58-37134-99

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