Package leaflet: Information for the user

Bupropion SUN 150 mg modified-release tablets
Bupropion SUN 300 mg modified-release tablets

bupropion hydrochloride

Read all of this leaflet carefully before you start using 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 <product name> is and what it is used for

<product name> is a medicine prescribed by your doctor to treat your depression. It's thought to interact with chemicals in the brain called *noradrenaline* and *dopamine*.

2. What you need to know before you take <product name>

Do not take <product name>:
- If you are allergic to bupropion or any of the other ingredients of this medicine (listed in section 6).
- If you are taking any other medicines which contain bupropion.
- If you have been diagnosed with epilepsy or have a history of seizures.
- If you have an eating disorder, or used to (for example, bulimia or anorexia nervosa).
- If you have a brain tumour.
- If you are usually a heavy drinker who has just stopped or are about to stop drinking.
- If you have severe liver problems.
- If you recently stopped taking sedatives, or if you are going to stop them while you're taking < p r o d u c t n a m e > .
- If you are taking or have been taking other medicines for depression 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 <product name>.

Warnings and precautions
Talk to your doctor or pharmacist before taking <product name>

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.

Serious skin reactions
Serious skin reactions, such as Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalised exanthematous pustulosis (AGEP) have been reported in association with <product name>. Stop using <product name> and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4

Children and adolescents
<product name> is not recommended to treat children or adolescents under 18 years of age.
There is an increased risk of suicidal thoughts and behaviour when children and adolescents under 18 years of age are treated with antidepressants.

Adults
Your doctor needs to know before you take <product name>:
- If you regularly drink a lot of alcohol.
- If you have diabetes for which you use insulin or tablets.
- If you have had a serious head injury or a history of head trauma.

<product name> has been shown to cause fits (seizures) in about 1 in a 1000 people. This side effect is more likely to occur in people from the groups listed above. If you have a fit during treatment you should stop taking <product name>. Do not take any more and see your doctor.
- If you have a bipolar disorder (extreme mood swings), as <product name> could bring on an episode of this illness.
- If you are taking other medicines for depression, the use of these medicines together with <product name> can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and <product name> " in this section).
- If you have liver or kidney problems, you may be more likely to get side effects.

If any of the above apply to you, talk to your doctor again before taking <product name>. He or she may want to pay special attention to your care, or recommend another treatment.

Thoughts of suicide 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 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.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years 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 might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

Other medicines and <product name>
If you are taking or have taken other antidepressants called *monoamine oxidase inhibitor*s (MAOIs) in the last 14 days, tell your doctor without taking <product name> (see also 'Do not take <product name> (in section 2).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, herbs or vitamins, including products you bought yourself. He or she may alter your dose of <product name>, or suggest a change in your other medications.

Some medicines don't mix with <product name>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 illness
- If you take theophylline for asthma or lung disease
- If you take tramadol, a strong painkiller

- If you have been taking sedatives, or if you are going to stop them while you're taking <product name> (see also 'Do not take <product name> in section 2)
- If you take medicines against malaria (such as mefloquine or chloroquine)
- If you take stimulants or other medicines to control your weight or appetite
- If you take steroids (by mouth or injection)
- If you take antibiotics called quinolones
- If you take some types of anti-histamines that can cause sleepiness
- If you take medicines for diabetes.

If any of these applies to you, talk to your doctor straight away, before taking <product name>. Your doctor will weigh up the benefits and risks to you of taking this medicine.

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). <product name> 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).
- If you take medicines for Parkinson's disease (levodopa, amantadine or orphenadrine)
- If you take medicines that affect your body's ability to breakdown <product name> (carbamazepine, phenytoin, valproate)
- If you take some medicines used to treat cancer (such as cyclophosphamide, ifosfamide)
- If you take ticlopidine or clopidogrel, mainly used to prevent stroke
- If you take some beta blockers (such as metoprolol)
- If you take some medicines for irregular heart rhythm (propafenone or flecainide)
- If you use nicotine patches to help you stop smoking.

If any of these applies to you, talk to your doctor straight away, before taking <product name>

<product name> 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 well <product name> is working for you. It may be necessary to increase your dose or change to another treatment for your depression. Do not increase your <product name> dose without advice from your doctor, as this may increase the risk of you having side effects, including seizures.

<product name> may make other medicines less effective

- If you take tamoxifen 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.

<product name> with alcohol

Alcohol can affect the way <product name> works and, when used together can rarely affect your nerves or your mental state. Some people find they are more sensitive to alcohol when taking <product name>. Your doctor may suggest you do not drink alcohol (beer, wine or spirits) while taking <product name>, or try to drink very little. But if you drink a lot now, do not stop suddenly: it may put you at risk of having a fit.

Talk to the doctor about drinking before you start taking <product name>

Effect on urine tests

<product name> may interfere with some urine tests to detect other drugs. If you require a urine test, tell your doctor or hospital that you are taking <product name>.

Pregnancy and breast-feeding
Do not take <product name> if you are pregnant, think you may be pregnant or are planning to have a baby unless your doctor recommends it. Ask your doctor or pharmacist for advice before taking this medicine. Some, but not all studies 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.

The ingredients of <product name> can pass into breast milk. You should ask your doctor or pharmacist for advice before taking <product name>

Driving and using machines
If <product name> makes you dizzy or light-headed, do not drive or operate any tools or machines.

<product name> contains lactose
<product name> contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take <product name>

Always take this medicine exactly as your doctor or pharmacist has told you. These are the usual doses, but your doctor's advice is personal to you. Check with your doctor or pharmacist if you are not sure.

It may take a while before you start feeling better. It takes time for the medicine to have its full effect, sometimes weeks or months. When you do start feeling better, your doctor may advise you to keep taking <product name> to prevent depression coming back.

How much to take
The usual recommended dose for adults only is one 150 mg tablet every day.
Your doctor may increase your dose to 300 mg every day if your depression does not improve after several weeks.

Take your dose of <product name> tablets in the morning. Do not take <product name> more than once each day.
The tablet is covered by a shell that slowly releases 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 your tablets whole. Do not chew them, crush them or split them if you do, there is a danger you could 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 stay on one 150 mg tablet every day for the whole of their treatment. Your doctor may have prescribed this if you have liver or kidney problems.

How long to take it for
Only you and your doctor can decide how long you should take <product name>. It may take weeks or months of treatment for you to see any improvement. Discuss your symptoms with your doctor regularly to decide how long you should be taking it. When you do start feeling better your doctor may advise you to keep taking <product name> to prevent depression coming back.

If you take more <product name> than you should
If you take too many tablets, you may increase the risk of a fit or seizure. Don't delay. Ask your doctor what to do or contact your nearest hospital emergency department at once.

If you forget to take <product name>
If you miss a dose, wait and take your next tablet at the usual time.
Do not take a double dose to make up for a forgotten tablet.

If you stop taking <product name>
Do not stop taking <product name> or reduce your dose without talking to your doctor first.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

Serious side effects
Fits or seizures
Approximately 1 in every 1000 people taking <product name> is at risk of a fit (a seizure or convulsion). The chance of this happening is higher if you take too much, if you take certain medicines, or if you are at higher than usual risk of fits. If you are worried, talk to your doctor.
➔ **If you have a fit,** tell your doctor when you have recovered. **Don't take any more tablets**.

Allergic reactions
Some people may get allergic reactions after intake of bupropion. These include
- Red skin or rash (like nettle rash) and itchy lumps (hives) on the skin
- Unusual wheezing or difficulty in breathing
- Swollen eyelids, lips or tongue
- Pains in muscles or joints
- Collapse or blackout.

➔ **If you have any signs of an allergic reaction** contact a doctor at once. **Don't take any more tablets**.

Allergic reactions can last a long time. If your doctor prescribes something to help with allergic symptoms, make sure you finish the course.

Serious skin reactions
Stop using bupropion and seek medical attention immediately if you notice any of the following symptoms:
- Very Rare - frequency: Reddish non-elevated, target like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome).
- Not known - frequency: Large areas of blistering and extensive skin peeling occur in a severe form of above described this serious skin reaction (toxic epidermal necrolysis).
- Not known - frequency: Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome). The onset of this syndrome is usually delayed (2-6 weeks after treatment initiation).
- Not known - frequency: A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis).

Lupus skin rash or worsening of lupus symptoms
Not known - frequency cannot be estimated from the available data in people taking <product name> 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 <product name> contact your doctor straight away, as it might be necessary to stop the treatment**

Other side effects
Very common side effects (may affect more than one in 10 people)
- Difficulty in sleeping (make sure you take <product name> in the morning)
- Headache
- Dry mouth
- Feeling sick, vomiting

Common side effects (may affect up to one in 10 people)
- Fever, dizziness, itching, sweating and skin rash (sometimes due to an allergic reaction)
- Shakiness, tremor, weakness, tiredness, chest pain
- Feeling anxious or agitated
- Tummy pain or other upsets (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 one in 100 people)
- Feeling depressed (see also section 2 'Take special care with <product name>, under 'Thoughts of suicide and worsening of your depression')
- Feeling confused
- Difficulty concentrating
- Raised heart rate
- Weight loss

Rare side effects (may affect up to one in 1,000 people)
- Seizures

Very Rare side effects (may affect up to one in 10,000 people)
- Palpitations, fainting
- Twitching, muscle stiffness, uncontrolled movements, problems with walking or coordination
- Feeling restless, irritable, hostile, aggressive, strange dreams, tingling or numbness, loss of memory
- Yellowing of 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 pains
- Changes in blood sugar levels
- Urinating more or less than usual
- Urinary incontinence (involuntary urination, leakage of urine)
- Worsening of psoriasis (thickened patches of red skin)
- feeling unreal or strange (*depersonalisation*); seeing or hearing things that are not there (*hallucinations*); sensing or believing things that are not true (*delusions*); severe suspiciousness (*paranoia*)

Frequency not known
Other side effects have occurred in a small number of people but their exact frequency is unknown:
- thoughts of harming or killing themselves while taking bupropion or soon after stopping
- treatment (see section 2, 'What you need to know before you take <product name>. If you have these thoughts, contact your doctor or go to a hospital straight away.
- loss of contact with reality and unable to think or judge clearly (psychosis); other symptoms
- may include hallucinations and/or delusions.
- stuttering
- reduced numbers of red blood cells (anaemia), reduced numbers of white blood cells
- (leucopenia) and reduced numbers of platelets (thrombocytopenia).
- blood sodium decreased (hyponatraemia).
- 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), while taking bupropion together with medicines used for treatment of depression (such as paroxetine, citalopram, escitalopram, fluoxetine and venlafaxine).

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 system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <product name>

Keep this medicine out of the sight and reach of children.

This medicine does not require any special temperature storage conditions.

Store it in the original pack in order to protect from moisture and light.

Do not use this medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

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

What <product name> contains
The active substance is bupropion hydrochloride. Each tablet contains 150 mg or 300 mg of bupropion hydrochloride.

The other ingredients are:
Tablet core: hydroxypropylcellulose, glycerol dibehenate, stearic acid.

Tablet coating: hypromellose, ethylcellulose, povidone K90, lactose monohydrate, triethyl citrate, methacrylic acid-ethyl acrylate coopolymer (1:1) Dispersion 30 %, macrogol 6000 and Silica, colloidal hydrated.

Printing ink material: shellac, black iron oxide (E 172), propylene glycol

What <product name> looks like and contents of the pack
<product name> 150 mg tablets are white to pale yellow, round, approximate 7.7 mm in diameter, coated tablets imprinted with ‘T’ in black ink on one side and plain on the other side.

<product name>300 mg tablets are. White to pale yellow, round, approximate 9.6 mm in diameter, coated tablets imprinted with ‘T1’ in black ink on one side and plain on the other side.

<product name> is supplied in the pack of:
White opaque plastic bottles. The bottle contains desiccant canister(s) containing activated silica gel & activated carbon. Please DO NOT EAT the canister(s)/content! The bottle is closed with a plastic child-resistant closure that include an induction seal liner.

150 mg: 30, 60, 90 tablets.

300 mg: 30, 60, 90 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

<[To be completed nationally]>

This leaflet was last revised in February 2026.