

Package leaflet: information for the user

Zyban, prolonged-release tablets 150 mg

bupropion hydrochloride

Read the entire 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.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not mentioned in this leaflet? Then contact your doctor or pharmacist.

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1. What is Zyban and what is it used for?
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1. What is Zyban and what is it used for?

Zyban is a medicine prescribed to help you stop smoking if you are also motivated, for example, by participating in a 'stop smoking' program.

Zyban will be most effective if you are fully motivated to quit smoking. Ask your doctor or pharmacist for advice on treatments and other support to help you quit.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

you are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet

you are using other medicines that contain bupropion (such as Wellbutrin XR to treat depression)

you suffer from a condition that causes seizures such as epilepsy or you have a history of seizures

you have or have had an eating disorder (for example, bulimia or anorexia nervosa)

you have severe liver problems, such as liver cirrhosis

you have a brain tumor

you are usually a heavy drinker who has recently stopped or plans to stop drinking while using Zyban

you have recently stopped using sedatives or medicines prescribed to treat anxiety (particularly so-called benzodiazepines or similar medicines), or you plan to stop using them while taking Zyban

you have a bipolar disorder (extreme mood swings), as Zyban can trigger an episode of this illness

you are using medicines for depression or Parkinson's disease called monoamine oxidase inhibitors (MAO inhibitors or MAOIs), or you have used them in the last 14 days. This period may be shorter for certain types of MAO inhibitors. Your doctor will advise you on this

→ If any of the above factors apply to you, inform your doctor immediately and do not use Zyban.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine. This is necessary because certain health conditions may mean you are more likely to experience side effects (see also section 4).

Brugada syndrome

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

Children and adolescents under 18 years

Zyban is not recommended for individuals under 18 years of age.

Adults

Seizures (convulsions)

Zyban is known to cause seizures (convulsions) in about 1 in 1,000 people (see also "Are you taking any other medicines?" later in this section and section 4 "Possible side effects" for further information). Seizures are more likely to occur:

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 have a history of head trauma (head injury)

If any of the above factors apply to you, do not use Zyban unless you have agreed with your doctor that there is a strong reason for you to use it.

If you have a seizure (convulsion) during treatment:

→ stop using Zyban and contact your doctor.

You have a higher chance of side effects:

if you have liver or kidney problems

if you are over 65

You will need to use a lower dosage (see section 3) and you will need to be closely monitored while using Zyban.

If you have had mental health problems...

Some people using Zyban have experienced hallucinations or delusions (seeing, hearing, or believing things that are not there), disturbed thoughts, or extreme mood swings. These effects are more likely to occur in people who have previously had mental health problems.

If you feel depressed or have suicidal thoughts...

Some people become depressed when they try to quit smoking; very rarely they may think about committing suicide, or attempt to do so. These symptoms mostly affect people using Zyban in the first few weeks of treatment. If you feel depressed, or think about suicide:

→ Contact your doctor immediately or go directly to the hospital.

If you are using antidepressant medications...

Using these medications together with Zyban can lead to serotonin syndrome, a potentially life-threatening condition (see "Are you taking any other medications?" in this section).

High blood pressure and Zyban...

Some people using Zyban have developed high blood pressure that needs to be treated. If you already have high blood pressure, it may worsen. The risk is higher if you also use nicotine patches to help you quit smoking.

Your blood pressure should be checked before you use Zyban. Also, during the use of Zyban, your blood pressure should be monitored, especially if you already have high blood pressure. If you also use nicotine patches, your blood pressure should be checked weekly. If your blood pressure rises, it may be necessary to stop using Zyban.

Are you taking any other medications?

Are you taking any other medications besides Zyban, including medications you bought without a prescription, have you done so recently, or are you planning to do so soon? If so, tell your doctor or pharmacist.

There may be a higher risk of seizures than usual:

if you are taking medications for depression or other mental health problems (see also the section

"When should you not use this medication?" at the beginning of section 2)

if you are using theophylline for asthma or lung disease

if you are using tramadol, a strong painkiller

if you are using medications against malaria

if you are using stimulant medications or other medications to control your weight or appetite

if you are using steroids (except creams or lotions for eye and skin conditions)

if you are using antibiotics called quinolones

if you are using certain types of antihistamines (mainly medications for allergies) that cause drowsiness

if you are using diabetes medication

→ If you are using medications from this list, contact your doctor immediately before using Zyban (see 'Some people need to use a lower dosage' in section 3).

Some medications affect the action of Zyban or may increase the risk of side effects, including:

medications for depression (such as desipramine, imipramine, paroxetine, citalopram, escitalopram, venlafaxine) or another mental disorder (such as risperidone,

thioridazine). Zyban can interact with some medications used for the treatment of depression, and you may experience changes in mental state (e.g., restlessness, hallucinations, coma) and other effects, such as a body temperature above 38 °C, increased heart rate, unstable blood pressure, and overactive reflexes, muscle stiffness, lack of coordination and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea)

medications for Parkinson's disease (levodopa, amantadine, or orphenadrine)
carbamazepine, phenytoin, or valproate, to treat epilepsy or certain mental disorders
some medications used for treating cancer (such as cyclophosphamide, ifosfamide)
ticlopidine or clopidogrel, mainly used to treat stroke or heart disease
certain beta-blockers (such as metoprolol), mainly used to treat high blood pressure
certain medications for an irregular heartbeat (such as propafenone or flecainide)
ritonavir or efavirenz, for the treatment of an HIV infection

→ If you are using medications from this list, contact your doctor. Your doctor will weigh the pros and cons of using Zyban for you or may decide to change the dose of the other medication you are taking.

Zyban can make other medications less effective:

if you are using tamoxifen for the treatment of breast cancer

If this applies to you, tell your doctor. It may be necessary to switch to another treatment to quit smoking.

if you are using digoxin for your heart

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

It may be necessary to reduce the dosage of some medications if you stop smoking
If you smoke, the chemicals absorbed into your body can make some medications less effective. If you stop smoking, it may be necessary to reduce the dosage of these medications; otherwise, you may experience side effects.

If you are using other medications, contact your doctor if you notice new symptoms that you think might be side effects.

What should you watch out for with alcohol?

Some people find that they are more sensitive to alcohol when using Zyban. Your doctor may advise you not to drink alcohol while using Zyban or to drink as little alcohol as possible. But if you currently drink a lot of alcohol, you should not stop suddenly: this can be risky and cause a seizure.

Effect on urine tests

Zyban can interfere with laboratory urine tests for other medications. If you need to have a laboratory urine test, tell your doctor or the hospital that you are using Zyban.

Pregnancy, breastfeeding, and fertility

Do not use Zyban if you are pregnant, planning to become pregnant, or think you might be pregnant.

Swallow the tablets whole. Do not chew, crush, or break the tablets; if you do, the medicine will be released into your body too quickly. This may increase your risk of side effects, including seizures.

Have you taken too much of this medicine?

If you take too many tablets, your risk of a seizure or another side effect may be increased.

→ Act immediately. Ask your doctor what to do or contact the nearest hospital emergency department immediately.

Have you forgotten to take this medicine?

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 dose.

If you stop taking this medicine

You may need to take Zyban for 7 weeks to achieve the full effect. Do not stop taking Zyban without consulting your doctor first. You may need to gradually reduce your dosage.

Do you have any other questions about using this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medicine, this medicine can cause side effects. Not everyone experiences them.

Serious side effects

Seizures (convulsions)

About 1 in 1,000 people using Zyban are at risk of a seizure. Symptoms of a seizure include convulsions and often loss of consciousness. Someone who has had a seizure may be confused afterward and may not remember what happened.

The chance of this happening is higher if you take too much, if you use certain other medicines, or if you have a higher risk of seizures than usual (see section 2).

→ If you have a seizure, let your doctor know once you have recovered. Do not take Zyban anymore.

Allergic reactions

Rarely, people (up to 1 in 1,000) may experience serious allergic reactions to Zyban.

Symptoms of allergic reactions include:

- rash (including an itchy rash with bumps); some forms of rash may require hospital treatment, especially if you also have a sore mouth or sore eyes
- unusual wheezing or breathing problems
- swollen eyelids, lips, or tongue
- pain in muscles or joints
- collapse (fainting) or a blackout

→ If you have signs of an allergic reaction, you should consult a doctor immediately. Do not take Zyban anymore.

Lupus rash or worsening of symptoms related to lupus

Not known – frequency cannot be determined with the available data on people using Zyban.

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

→ If you experience lupus flare-ups, rash, or lesions (especially in areas exposed to sunlight) while using Zyban, contact your doctor immediately, as it may be necessary to stop the treatment.

Acute Generalized Exanthematous Pustulosis (AGEP)

Not known – frequency cannot be determined with the available data on people using Zyban.

Symptoms of AGEP include a rash with pus-filled pustules/blisters.

→ If you have a rash with pus-filled pustules/blisters, contact your doctor immediately, as it may be necessary to stop the treatment.

Other side effects

Very common side effects

These may affect more than one in 10 people:

sleep problems (do not take Zyban just before going to bed)

Common side effects

These may affect up to one in 10 people:

feeling depressed (see also “When should you be extra careful with this medicine?” in section 2)

feeling anxious or agitated

concentration problems

feeling unsteady (trembling)

headache

feeling sick (nausea), vomiting

stomach pain or other problems (such as constipation), changes in the taste of food, dry mouth

fever, dizziness, sweating and skin rash (sometimes due to an allergic reaction), itching

Uncommon side effects

These may affect up to one in 100 people:

ringing in the ears, vision problems

increase in blood pressure (sometimes severe), flushing

loss of appetite (anorexia)

weakness

chest pain

confusion

increased heart rate

Rare side effects

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

seizures (see the beginning of this section)

muscle twitching, muscle stiffness, uncoordinated muscle activity, problems with walking or coordination (ataxia)

palpitations

fainting, feeling weak when standing up suddenly due to a rapid drop in blood pressure

irritation or hostility; abnormal dreams (including nightmares)

- memory loss
- tingling or numbness
- severe allergic reactions; rash combined with joint and muscle pain (see the beginning of this section)
- urinating more or less frequently than usual
- severe rash in the mouth and on other parts of the body. This rash can be life-threatening
- worsening of psoriasis (thickened patches of red skin)
- yellowing of the skin or whites of the eyes (jaundice), elevated liver enzymes, hepatitis
- changes in blood sugar levels
- feeling unreal or strange (depersonalization); seeing or hearing things that are not there (hallucinations)

Very rare side effects

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

- feeling restless or aggressive
- feeling or believing things that are not true (delusions), severe suspicion (paranoia)
- urinary incontinence (unexpected urination, urine leakage)
- unusual hair loss or thinning of the hair (alopecia).

Frequency not known

A small number of people have experienced other side effects, the frequency of which is not precisely known:

- thoughts of harming oneself or committing suicide while using Zyban or shortly after stopping Zyban (see section 2 "When should you not use this medicine or be extra careful?"). If you have these thoughts, contact your doctor immediately or go to a hospital immediately
- loss of contact with reality and inability to think clearly or judge (psychosis); other symptoms may include hallucinations and/or delusions
- feeling of sudden and intense fear (panic attack)
- stuttering
- reduced number of red blood cells (anemia), reduced number of white blood cells (leukopenia) and reduced number of platelets (thrombocytopenia)
- low sodium levels in the blood (hyponatremia)
- changes in mental state (e.g., restlessness, hallucinations, coma) and other effects, such as body temperature above 38 °C, increased heart rate, unstable blood pressure, and overactive reflexes, muscle stiffness, lack of coordination and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea), while using Zyban together with medications for the treatment of depression (such as paroxetine, citalopram, escitalopram, fluoxetine, and venlafaxine).

Effects of quitting smoking

People who quit smoking sometimes experience nicotine withdrawal symptoms. This can also occur in people using Zyban. Signs of nicotine withdrawal symptoms include:

- sleep problems
- muscle twitches or sweating
- feeling anxious, agitated, or depressed, sometimes with suicidal thoughts

If you are concerned about how you feel, contact your doctor.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you help us gather more information about the safety of this medicine.

5. How do you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find this on the packaging. It includes a month and a year. The last day of that month is the expiry date.

Store Zyban tablets in the original packaging below 25 °C.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed correctly and do not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

The active substance in this medicine is bupropion hydrochloride.

The other substances in this medicine are:

tablet core	-	microcrystalline cellulose, hypromellose, cysteine hydrochloride monohydrate, magnesium stearate
tablet coating	-	hypromellose, macrogol 400, titanium dioxide (E171), carnauba wax
printing ink	-	hypromellose, black iron oxide (E172)

What does Zyban look like and what is in a package?

A Zyban 150 mg tablet is a medicine in the form of a white, film-coated, biconvex, round tablet with the text "GX CH7" on one side. The tablets are available in boxes containing blisters with 30, 40, 50, 60, or 100 tablets.

It is possible that not all pack sizes are marketed.

Zyban is registered under number RVG 24160.

Marketing authorization holder and manufacturer

Marketing authorization holder:

GlaxoSmithKline BV
Van Asch van Wijckstraat 55H
3811 LP Amersfoort
033 2081100

Manufacturer:

Glaxo Wellcome S.A.
Avenida de Extremadura 3
09400 Aranda de Duero
Burgos
Spain

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This medicine is registered in member states of the European Economic Area under the following names:

Zyban: Belgium, Denmark, Germany, Finland, France, Greece, Ireland, Iceland, Italy, Luxembourg, Netherlands, Norway, Portugal, Sweden
Zyntabac: Netherlands, Spain

This leaflet was last approved in March 2024.

More information about this medicine can be found on the website of the Medicines Evaluation Board: www.cbg-meb.nl