Package leaflet: Information for the user

Zyban

150 mg prolonged release tablets

bupropion hydrochloride

- 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

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

What is in this leaflet

1. What Zyban is and what it is used for
2. What you need to know before you take Zyban
3. How to take Zyban
4. Possible side effects
5. How to store Zyban
6. Contents of the pack and other information

1. What Zyban is and what it is used for

Zyban is a medicine prescribed to help you stop smoking, when you also have motivational support such as taking part in a 'stop smoking' programme.

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

2. What you need to know before you take Zyban

Don't take Zyban:

- **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 a condition that causes fits *(seizures)*,** such as **epilepsy,** or if you have a history of fits
- **if you have an eating disorder** or had one in the past (for example, bulimia or anorexia nervosa)
- **if you have severe liver problems**, such as *cirrhosis*
- **if you have a brain tumour**
- **if you are usually a heavy drinker** and you have just stopped drinking alcohol, or are going to stop while you're taking Zyban
- **if you have recently stopped taking sedatives** or **medicines to treat anxiety** (especially *benzodiazepines* or similar medicines), or if you are going to stop them while you're taking Zyban
- **if you have a bipolar disorder** (extreme mood swings) as Zyban could bring on an episode of this illness
- **if you are taking medicines for depression** or Parkinson's disease called *monoamine oxidase inhibitors (MAOIs)*, or have taken them in the last 14 days. The timing may be shorter for some types of MAOIs, your doctor will advise you.
- **if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores** after taking Zyban or other related medicines.

→ **If any of these applies to you, talk to your doctor straight away, and don't take Zyban**.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Zyban. This is because some conditions make it more likely that you will have side effects (see also section 4).

Serious skin reactions

This medicine can cause serious skin reactions. Stop using Zyban and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

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.

Children and adolescents

Zyban is not recommended for people under 18 years.

Adults

Fits *(seizures)*

Zyban has been shown to cause fits (seizures) in about 1 in 1,000 people. (See also Other medicines and Zyban later in this section and section 4 Possible side effects, for more information).

Fits are more likely:

- **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.

If any of these applies to you, don't take Zyban unless you have agreed with your doctor that there is a strong reason for doing so.

If you have a fit (seizure) during treatment:

→ **Stop taking Zyban and don't take any more. See your doctor**.

You may have more risk of side effects:

- **if you have kidney or liver problems**
- **if you are aged over 65.**

You will need to take a lower dose (see section 3) and be checked closely while you are taking Zyban.

If you have had any mental health problems…

Some people taking Zyban have had hallucinations or delusions (seeing, hearing or believing things that are not there), disordered thoughts or extreme mood swings. These effects are more likely in people who have had mental health problems before.

If you feel depressed or suicidal…

Some people become depressed when they try to stop smoking; very occasionally, they may think about committing suicide, or try to do so. These symptoms have affected people taking Zyban, most often in the first few weeks of treatment.

If you feel depressed or think about suicide:

→ **Contact your doctor or go to a hospital straight away**.

If you are taking medicines for depression…

The use of these medicines together with Zyban can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Zyban" in this section).

High blood pressure and Zyban…

Some people taking Zyban have developed high blood pressure which needs treatment. If you already have high blood pressure, it can become worse. This is more likely if you are also using **nicotine patches** to help you stop smoking.

OPEN THE LEAFLET

Section 2 continues overleaf…

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from page 1

Section 2, What you need to know before you take Zyban, continued…

You will have your blood pressure checked before you take Zyban and while you are taking it, especially if you already have high blood pressure. If you are also using nicotine patches, your blood pressure needs to be checked every week. If your blood pressure increases, you may need to stop taking Zyban.

Other medicines and Zyban

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines you bought without a prescription.

There may be a higher than usual risk of fits if you take:

- medicines for **depression** or **other mental health problems** (see also Don't take Zyban at the beginning of section 2)
- **theophylline** for **asthma** or **lung disease**
- **tramadol**, a strong painkiller
- medicines against **malaria**
- **stimulants** or other medicines to control your **weight or appetite**
- **steroids** (except creams and lotions for eye and skin conditions)
- **antibiotics** called **quinolones**
- **some types of anti-histamines** mainly used to treat allergies, that can cause sleepiness
- medicines for **diabetes**.

→ **If you take any medicines in this list, talk to your doctor straight away**, before you take Zyban (see section 3 under Some people need to take a lower dose).

Some medicines can affect how Zyban works, or make it more likely that you'll have side effects. These include:

- medicines for **depression** (such as desipramine, imipramine, paroxetine, citalopram, escitalopram, venlafaxine) or **other mental health problems** (such as risperidone, thioridazine). Zyban 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)
- medicines for **Parkinson's disease** (such as levodopa, amantadine or orphenadrine)
- **carbamazepine**, **phenytoin** or **valproate,** to treat **epilepsy** or some **mental health problems**
- some medicines used to treat **cancer** (such as cyclophosphamide, ifosphamide)
- **ticlopidine** or **clopidogrel**, mainly used to treat **heart disease** or **stroke**
- some **beta blockers** (such as metoprolol), mainly used to treat high blood pressure
- some medicines for **irregular heart rhythm** (such as propafanone, flecainide)
- **ritonavir** or **efavirenz,** for treatment of HIV infection.

→ **If you take any medicines on this list, check with your doctor.** Your doctor will weigh up the benefits and risks to you of taking Zyban, or may decide to change the dose of the other medicine you are taking.

Zyban 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 smoking cessation.

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

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

The dose of some medicines may need to be reduced when you stop smoking

When you smoke, the chemicals absorbed into your body can cause some medicines to be less effective. When you stop smoking, your dose of these medicines may need to be reduced; otherwise, you may get side effects.

If you are taking any other medicines, check with your doctor if you notice any new symptoms that you think may be side effects.

Zyban with alcohol

Some people find they are more sensitive to alcohol while taking Zyban. Your doctor may suggest you do not drink alcohol while you're taking Zyban, or try to drink as little as possible. If you do drink a lot now, don't just stop suddenly, because that may put you at risk of having a fit.

Effect on urine tests

Zyban 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 Zyban.

Pregnancy and breast-feeding

Don't take Zyban if you are pregnant, think you may be pregnant or are planning to have a baby. 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 Zyban. It is not known if these are due to the use of Zyban.

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

Driving and using machines

Some of the side effects of Zyban, such as feeling dizzy or light-headed, may affect your concentration and judgement.

If you are affected, don't drive or operate machinery.

3. How to take Zyban

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

When to start and how much to take

- **Start taking Zyban while you are still smoking**
- **Set a Target Stop Smoking Day ideally during the second week** you're taking it

Week 1 **Ideally keep smoking while taking Zyban**	**Days 1 to 6**	Take **one tablet** (150 mg), **once a day**
	Day 7	Increase your dose to **one tablet, twice a day**, at least 8 hours apart, and **not near to bedtime**
Week 2	Carry on taking **one tablet, twice a day**. Stop smoking this week, on your **Target Stop Smoking Day**.	
Weeks 3 to 9	Carry on taking **one tablet, twice a day** for **up to 9 weeks**. If you have not been able to stop smoking after **7 weeks**, your doctor will advise you to stop taking Zyban. You may be advised to stop taking Zyban gradually, after 7 - 9 weeks.	

Some people need to take a lower dose

as they may be more likely to get side effects.

- if you are aged over 65
- if you have liver or kidney disease
- if you have a higher risk of fits (see Warnings and Precautions and Other medicines and Zyban in section 2)

the maximum recommended dose for you is **one 150 mg tablet once a day.**

How to take your tablets

Take your Zyban tablets at least 8 hours apart. Don't take Zyban near to bedtime - it may cause difficulty in sleeping.

You can take Zyban with or without food.

Swallow your Zyban tablets whole. Don't chew them, crush them or split them - if you do, the medicine will be released into your body too quickly. This will make you more likely to have side effects, including fits.



If you take more Zyban than you should

If you take too many tablets, you may be more likely to have a fit or other side effects.

→ **Don't delay**. Contact your doctor or your nearest hospital emergency department immediately.

If you forget to take Zyban

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 Zyban

You may need to take Zyban for as long as 7 weeks to have its full effect.

Don't stop taking Zyban without talking to your doctor first. You may need to reduce your dose gradually.

If you have any further questions about using 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 (seizures)

Approximately 1 in every 1,000 people taking Zyban is at risk of having a fit.

Symptoms of a fit include convulsions and usually loss of consciousness. Someone who has had a fit may be confused afterwards and may not remember what has happened.

Fits are more likely if you take too much, if you take some other medicines or if you are at higher than usual risk of fits (see section 2).

➔ **If you have a fit**, tell your doctor when you have recovered. **Don't take any more Zyban**.

Allergic reactions

Rarely (up to 1 in 1,000) people may have potentially serious allergic reactions to Zyban. Signs of allergic reactions include:

- skin rash (including itchy, bumpy rash).
- 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**.

Serious skin reactions

Stop using bupropion and seek medical attention immediately if you notice any of the following symptoms:

- Frequency rare: 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*)
- Frequency not known: Large areas of blistering and extensive skin peeling occur in a severe form of above described serious skin reaction (*toxic epidermal necrolysis*)
- Frequency not known: 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)
- Frequency not known: 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 Zyban.

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 Zyban contact your doctor straight away, as it might be necessary to stop the treatment.**

Other side effects

Very common side effects

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

- difficulty in sleeping (make sure you don't take Zyban near to bedtime).

Common side effects

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

- feeling depressed (see also '*Warnings and Precautions*' in section 2)
- feeling anxious or agitated
- difficulty concentrating
- feeling shaky (tremor)
- headache
- feeling sick (nausea), being sick (vomiting)
- stomach pain or other upsets (such as constipation), changes in the taste of food, dry mouth
- fever, dizziness, sweating, 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, visual disturbances
- increase in blood pressure (sometimes severe), flushing
- loss of appetite *(anorexia)*
- feeling weak
- chest pain
- feeling confused
- rapid heartbeat.

Rare side effects

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

- fits (see the beginning of this section)
- twitching, muscle stiffness, uncontrolled movements, problems with walking or coordination *(ataxia)*
- palpitations
- fainting, feeling faint when you stand up suddenly, because your blood pressure falls
- feeling irritable or hostile; strange dreams (including nightmares)
- loss of memory
- tingling or numbness
- severe allergic reactions; rash together with joint and muscle pains (see the beginning of this section)
- urinating (passing water) more or less than usual
- worsening of psoriasis (thickened patches of red skin)
- your skin or the whites of your eyes turning yellow (jaundice), increase in liver enzymes, hepatitis
- changes in blood sugar levels
- feeling unreal or strange *(depersonalisation)*; seeing or hearing things that are not there *(hallucinations)*.

Very rare side effects

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

- feeling restless, aggressive
- sensing or believing things that are not true *(delusions)*; severe suspiciousness *(paranoia)*.
- urinary incontinence (involuntary urination, leakage of urine)
- unusual hair loss or thinning *(alopecia)*.

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 Zyban or soon after stopping treatment (see section 2, What you need to know before you take Zyban). 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.
- feeling of sudden and intense fear (*panic attack*)
- reduced number of red blood cells (anaemia), reduced number of white blood cells (leucopenia) and reduced number of platelets (thrombocytopenia).
- stuttering.
- 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 Zyban together with medicines used for treatment of depression (such as paroxetine, citalopram, escitalopram, fluoxetine and venlafaxine).

Effects of giving up smoking

People who stop smoking are often affected by nicotine withdrawal. This can also affect people taking Zyban. Signs of nicotine withdrawal include:

- difficulty in sleeping
- tremor or sweating
- feeling anxious, agitated or depressed, sometimes with thoughts of suicide.

Talk to your doctor if you have any concerns about how you feel.

TURN OVER

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zyban

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

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 store this medicine above 25 °C.

Store it in the original package.

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 information

What Zyban contains

Each tablet contains 150 mg of the active substance, bupropion hydrochloride.

The other ingredients are:
Tablet core; microcrystalline cellulose, hypromellose, cysteine hydrochloride monohydrate, magnesium stearate.
Tablet coating; hypromellose, macrogol 400, titanium dioxide (E171), carnauba wax.
Printing ink; hypromellose, iron oxide black (E172).

What Zyban looks like and contents of the pack

Zyban 150 mg tablets are white, film-coated, biconvex, round tablets imprinted with 'GX CH7' on one side. They are available in cartons containing blisters of 60 tablets.

Marketing authorisation holder and manufacturer

Glaxo Wellcome UK Limited, GSK Medicines Research Centre, Gunnels Wood Road, Stevenage Hertfordshire, SG1 2NY, UK is licensed to sell Zyban in the UK
The tablets are made by Glaxo Wellcome S.A., Avenida de Extremadura, 3, 09400 Aranda de Duero, Burgos, Spain

Useful contacts

A number of organisations exist that can offer support now that you have decided to stop smoking. Contact details of some of these organisations are given below:
NHS Stop Smoking Service - http://smokefree.nhs.uk
Action on Smoking and Health (ASH) - http://www.ash.org.uk
QUIT - http://www.quit.org.uk

Other formats

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name	**Zyban 150 mg tablets**
Reference number	10949/0340

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in **August 2026.**

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