

# ZYBAN<sup>®</sup> TABLETS

Bupropion hydrochloride 150mg

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## Consumer Medicine Information

Please read this leaflet carefully before you start taking Zyban tablets.

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### What is in this leaflet

This leaflet answers some common questions about Zyban tablets. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist (also known as a chemist).

All medicines have benefits and risks. Sometimes new risks are found even when a medicine has been used for many years. Your doctor has weighed the risks of you using Zyban tablets against the expected benefits it will have for you.

If you have any concerns about taking this medicine, or experience any difficulties during or after using this medicine, tell your doctor or pharmacist.

This medicine is only one part of a general plan to help you manage your smoking habit. You should discuss this plan with your doctor.

**Keep this leaflet with your Zyban tablets. You may need to read it again.**

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### What is in your medicine

Zyban tablets contain the active ingredient *bupropion* (as bupropion hydrochloride).

The other ingredients are: microcrystalline cellulose, hypromellose, cysteine hydrochloride monohydrate, magnesium stearate, macrogol,

titanium dioxide (E171), carnauba wax, polyethylene glycol, edible black ink.

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### What are Zyban tablets used for

Your doctor has chosen this medicine to suit you and your condition.

Zyban is a medicine prescribed by your doctor to help you stop smoking. Studies have shown that a significant number of people managed to remain smoke-free for at least 6 months while taking Zyban. For many patients, Zyban reduces withdrawal symptoms and the urge to smoke.

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### How Zyban works

Zyban reduces the craving for smoking and so helps you to stop smoking. Its exact mechanism of action is not fully understood, but it is believed that it interacts with chemicals in the brain called noradrenaline and dopamine, which are associated with craving and withdrawal.

Your doctor may have prescribed Zyban for another reason. If you have any questions about why Zyban tablets have been prescribed for you, ask your doctor.

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### When you must not take Zyban

Do not take Zyban if you answer "Yes" to any of the following questions and consult your doctor before taking this medicine.

- Have you been told that you are allergic to Zyban, bupropion, or any of the other ingredients in Zyban tablets?
- Have you had any seizures in the past or currently have a seizure disorder?
- Have you had a head injury or brain tumour?
- Do you have or have had an eating disorder (for example, bulimia or anorexia nervosa)?
- Are you taking stimulants or medicines to control your weight?
- Are you currently taking or have recently taken a monoamine oxidase inhibitor (MAOI)? If you are, you will need to wait at least 14 days before starting to take Zyban.
- Are you taking any other medicine containing bupropion?
- Are you undergoing withdrawal from alcohol, or sedatives (medicines that calm you).

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### Before you take Zyban

Tell your doctor if:

- You have liver or kidney problems
- You are a heavy drinker or you want to drink alcohol whilst taking Zyban
- You take sedatives
- You have diabetes and you are taking insulin or medicines used to control your blood sugar levels. Zyban may affect your blood glucose levels.

- You are pregnant or likely to become pregnant soon
- You are breastfeeding
- You suffer from bi-polar disorder (manic-depression)
- You are taking other medications or herbal remedies, including those you buy from a supermarket, pharmacy or health food store (see also under “Side Effects” section). This also includes nicotine patches.
- You are taking ritonavir or efavirenz, medicines used to treat HIV infection.

Zyban may affect other medicines you may be taking.

### **How to take Zyban tablets**

Take your medicine as your doctor has told you. The usual recommended dose is one 150-mg tablet each day for the first 3 days. On the fourth day, begin taking one 150-mg tablet twice daily. Doses should be taken **at least** 8 hours apart.

Insomnia (sleeplessness) is a very common side effect of taking Zyban. It is often temporary. You can reduce the likelihood of insomnia by avoiding taking a Zyban tablet at bedtime (as long as the second dose is taken 8 hours **after** the first dose). Your doctor may also reduce your Zyban dose if needed.

It takes about 1 week for Zyban to reach the right levels in your body to be effective. So, to maximize your chance of stopping, you should not stop smoking until you have been taking Zyban for 1 week. You should set a date to stop smoking during the second week you’re taking Zyban.

Most people should take Zyban for at least 7 weeks.

Follow your doctor’s instructions.

The label on your medicine will usually tell you how much to take and how often. If you are not sure ask your doctor or pharmacist.

Zyban and nicotine patches should only be used together under the supervision of your doctor.

Swallow Zyban Tablets whole. **Do not chew, divide, or crush tablets.**

### **What to do if you take too much? (overdose)**

It is important to keep to the dose on the label of your medicine.

Do not take more tablets than your doctor prescribed. If you accidentally take too many tablets even if there are no signs of discomfort or poisoning, such as drowsiness, hallucinations and loss of consciousness ask your doctor what to do or contact your nearest hospital emergency department or poisons centre (**0800 POISON or 0800 764 766**) for advice. Keep telephone numbers for these places handy. If you are not sure what to do, contact your doctor or pharmacist.

### **What if you miss a dose**

You must take your Zyban tablets every day as prescribed by your doctor. If you forget to take a dose, **do not** take a tablet to “catch up” for the dose you forgot. Wait and take your next tablet at the usual time.

### **Side-Effects**

Most people taking this medicine find that it causes no problems. As with all

medicines, a few people may find that it causes side effects.

There is a chance that approximately 1 out of every 1000 people taking bupropion hydrochloride, the active ingredient in Zyban, will have a seizure. The chance of this happening increases if you:

- Have or have had a seizure disorder (for example, epilepsy);
- Have or have had an eating disorder (for example, bulimia or anorexia nervosa);
- Take more than the recommended amount of Zyban
- Suddenly stop taking sedatives/tranquillisers after long-term use
- are taking any other medicine containing bupropion
- Are taking any other medicines known to lower the seizure threshold such as antipsychotics, antidepressants, antimalarials (medicines used for the treatment of malaria), theophylline (used in asthma), systemic steroids, tramadol (an analgesic), quinolones (antibiotic medications) and sedating antihistamines.

You can reduce the chance of experiencing a seizure by giving your doctor the information they need and following carefully your doctor’s directions on how to take Zyban.

Some of the side effects associated with Zyban can also be related to nicotine withdrawal symptoms, a result of giving up smoking.

The most common side effects which may occur with Zyban are:

Headache, difficulty sleeping, dry mouth, upset stomach

(example nausea, vomiting and constipation).

The following side effects have also been reported:

Fever, tiredness, chest pain, accelerated heart beat, fall or increase in blood pressure, flushing, shakiness, dizziness, depression, confusion, memory impairment, tingling sensations in the hands or feet, seizures, inability to sleep, agitation, irritability, hostility, depersonalisation, loss of concentration, anxiety, lack of appetite, ringing in the ears, jerky movements, twitching, abnormal dreams, urge to pass urine frequently or retention, impaired vision, taste disorder, jaundice, hepatitis. In addition, itching, sweating and skin rash have been reported, alone or in association with joint pains and muscle pains.

Very rarely, patients may experience a depressed mood and suicidal thoughts. However, depressed mood may also be a symptom of nicotine withdrawal and quitting smoking. This generally happens in the early stages of quitting smoking.

If you think you are having an allergic (hypersensitivity) reaction to Zyban, TELL YOUR DOCTOR IMMEDIATELY. Symptoms include:

- Severe skin rash, itching or hives
- Swelling of the face, lips, mouth or throat
- Difficulty breathing and swallowing
- Fever
- Low blood pressure

If these symptoms occur stop taking the tablets immediately and contact your doctor. Discuss any troublesome side effects with your doctor or pharmacist.

## Driving and operating machinery

Do not drive a car or operate machinery until you know if Zyban affects your ability to perform these tasks.

If you have any other symptoms that you do not understand or you feel unwell in any other way, tell your doctor or pharmacist.

## Laboratory Tests

Zyban may interfere with some laboratory tests to detect other drugs. If you require a laboratory test, tell your doctor or hospital that you are taking Zyban.

## Storage

Do not use Zyban tablets after the expiry date.

Keep your medicine at room temperature, out of direct sunlight and heat. Do not leave it in the car or on window sills.

Keep it where children cannot reach it. It may harm them.

If your doctor tells you to stop using Zyban or the product has passed its expiry date, ask your pharmacist what to do with any Zyban left over.

## Remember

This medicine is for you. Never give it to someone else. It may not be suitable for them.

**Do not stop using Zyban or change the dose without first checking with your doctor.**

## Further Information

It is not dangerous to smoke and use Zyban at the same time. However, continuing to smoke after the date you set to stop smoking will seriously

reduce your chance of breaking your smoking habit.

Using Zyban Tablets and nicotine patches together may raise your blood pressure. Your doctor will probably want to check your blood pressure regularly to make sure that it stays within acceptable levels.

**Zyban is not recommended for women who are pregnant or breast-feeding.** Women should notify their doctor if they become pregnant or intend to become pregnant while taking Zyban.

**It is best not to drink alcohol at all or to drink very little while taking Zyban.** If you drink a large quantity of alcohol or suddenly stop drinking after long periods of regular intake, you may increase your chance of having a seizure. Therefore, it is important to discuss your use of alcohol with your doctor before you begin taking Zyban.

## Sponsor

Zyban tablets are supplied by:

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This leaflet was prepared on:  
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You may need to read this leaflet again. Please do not throw it away until you have finished your medicine.

This leaflet does not tell you everything about your medicine. If you have any

questions or are not sure about anything, then ask your doctor or pharmacist.

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