

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using ZYBAN?

ZYBAN contains the active ingredient bupropion hydrochloride. ZYBAN is a medicine prescribed by your doctor to help you stop smoking.

For more information, see Section [1. Why am I using ZYBAN?](#) in the full CMI.

### 2. What should I know before I use ZYBAN?

Do not use if you have ever had an allergic reaction to bupropion or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use ZYBAN?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ZYBAN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use ZYBAN?

- It is recommended that treatment is started while you are still smoking and a “target stop date” set within the first two weeks of treatment with ZYBAN.
- The usual initial dose is 150 mg taken daily for three days increasing to 150 mg twice daily for at least 7 weeks.

More instructions can be found in Section [4. How do I use ZYBAN?](#) in the full CMI.

### 5. What should I know while using ZYBAN?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ZYBAN.</li><li>• Tell any other doctors, dentists, pharmacists and anaesthetists who treat you that you are taking this medicine.</li><li>• If you become pregnant while taking this medicine, tell your doctor immediately.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not take ZYBAN to treat any other complaints unless your doctor tells you to.</li><li>• Do not stop taking your medicine or lower the dosage without checking with your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how ZYBAN affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Be careful when drinking alcohol while you are taking this medicine.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your tablets in the original package, in a cool dry place below 25°C away from moisture, heat or sunlight. Keep it where children cannot reach it.</li></ul>

For more information, see Section [5. What should I know while using ZYBAN?](#) in the full CMI.

### 6. Are there any side effects?

Side effects that have been reported to be less serious include difficulty sleeping, headache, dry mouth, nausea, vomiting, panic attacks and weight loss. More serious side effects include loss of memory, muscle spasms, swelling of the face, lips, tongue, mouth, throat or eyelids, low blood pressure, difficulty breathing, fainting, pain in muscles or joints, fits, lupus flares and severe skin rash.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# ZYBAN

Active ingredient: *bupropion hydrochloride*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using ZYBAN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ZYBAN.**

Where to find information in this leaflet:

- [1. Why am I using ZYBAN?](#)
- [2. What should I know before I use ZYBAN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ZYBAN?](#)
- [5. What should I know while using ZYBAN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using ZYBAN?

ZYBAN contains the active ingredient **bupropion hydrochloride**. ZYBAN is a selective noradrenaline and dopamine reuptake inhibitor.

**ZYBAN is a medicine prescribed by your doctor to help you stop smoking.**

For many patients, ZYBAN reduces withdrawal symptoms and the urge to smoke. It is not the same as nicotine replacement treatments; instead, it is thought to act in the brain to decrease cravings.

ZYBAN will be most effective if you are fully committed to giving up smoking, and if you have suitable support — for example, a ‘stop smoking’ support programme.

Ask your doctor or pharmacist for advice on treatments and other support to help you give up smoking.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

### 2. What should I know before I use ZYBAN?

#### Warnings

**Do not use ZYBAN if:**

- you are allergic to bupropion (active ingredient), or any of the ingredients listed at the end of this leaflet.
- if you have a condition that causes fits, such as epilepsy.
- if you have or had a head injury or 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 (medicines that calm you), or if you are going to stop them while you’re taking ZYBAN.
- if you’re taking any other medicines which contain bupropion.
- if you have an eating disorder, or had one in the past (for example, bulimia or anorexia nervosa).
- 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.
- if the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of these medical conditions:**

#### Fits (seizures)

ZYBAN has been shown to cause fits in about 1 in 1000 people. While taking ZYBAN, fits are more likely if you:

- regularly drink a lot of alcohol
- regularly take sedatives
- have diabetes for which you use insulin or tablets
- take stimulants or other medicines to control your weight or appetite
- have a brain tumour
- have a history of fits
- have ever had a serious head injury
- take medicines that are known to increase the chance of having a fit.

If you have a fit during treatment stop taking ZYBAN and speak to your doctor.

#### Liver problems, kidney problems, or over the age of 65

Tell your doctor if any of the above applies to you. You may need to take a lower dosage and be checked more closely while taking ZYBAN.

#### Mental health problems

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

#### Feel depressed or suicidal

Some people become depressed when they try to stop smoking; very occasionally, they may think about

committing suicide. 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 hospital straight away.**

### **Brugada syndrome**

Tell your doctor 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.

**If you have not told your doctor about any of the above, tell him/her before you start taking ZYBAN.**

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### **Pregnancy and breastfeeding**

**Do not take this medicine if you are pregnant or plan to become pregnant.**

Your doctor will discuss the risks and benefits of using ZYBAN if you are pregnant. 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.

**Do not breast-feed if you are taking this medicine.**

Breastfeeding is not recommended while you are taking ZYBAN. The active ingredient, bupropion, can pass into breast milk and there is a possibility that your baby may be affected.

### **Children**

**Do not give this medicine to a child under the age of 18 years.**

Safety and effectiveness in children younger than 18 years have not been established.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

## **3. What if I am taking other medicines?**

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.**

**Some medicines may interfere with ZYBAN and affect how it works. These include:**

- nicotine replacement therapy, such as nicotine patches
- stimulants or other medicines to control your weight or appetite
- medicines for diabetes, including insulin

- medicines for depression or other mental health problems
- medicines for Parkinson's disease (such as levodopa, amantadine)
- medicines for epilepsy (such as carbamazepine, phenytoin)
- medicines used to treat cancer (such as tamoxifen)
- beta-blockers, mainly used to treat high blood pressure (such as metoprolol)
- medicines for irregular heart rhythm
- ticlopidine or clopidogrel, mainly used for heart disease or stroke
- medicines used to treat HIV infection (such as ritonavir, efavirenz).

These medicines may be affected by ZYBAN or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

## **4. How do I use ZYBAN?**

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions, ask your doctor or pharmacist for help.**

### **How much to take**

**Take your medicine as your doctor has told you.**

**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**

Keep smoking while taking ZYBAN.

#### **Day 1 to 3:**

Take one tablet (150 mg), once a day.

#### **Day 4 to 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**.

#### **Week 3**

Carry on taking one tablet, twice a day for at least 7 weeks. Your doctor may then decide that you should continue to take ZYBAN for longer.

If you have not been able to stop smoking after 7 weeks, your doctor may advise you to stop taking ZYBAN, as it is unlikely to work for you during this stop smoking attempt.

**Some people may need to take a lower dose of ZYBAN to reduce the risk of side effects:**

- if you are aged over 65
- if you have liver or kidney disease

**Tell your doctor or pharmacist if either of these applies to you.**

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.

## **When to take ZYBAN**

**Take your medicine at about the same time each day.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

## **How to take ZYBAN**

**Swallow the ZYBAN tablet whole.**

Do not chew, divide, or crush tablets as the medicine will be released into your body too quickly. This will make you more likely to have side effects, including fits.

## **How long to take it**

**Your doctor will tell you how long you should take ZYBAN for.**

Most people should take ZYBAN for at least 7 weeks. Your doctor may decide that you should continue to take ZYBAN for longer.

**Speak to your doctor before you stop taking ZYBAN.**

## **If you forget to use ZYBAN**

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose that you missed.**

**If you are not sure what to do, ask your doctor or pharmacist.**

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

## **If you take too much ZYBAN**

**Do not take more tablets than your doctor prescribed.**

If you accidentally take too many ZYBAN tablets, you may be more likely to have side effects, including fits, drowsiness, and loss of consciousness.

**Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much ZYBAN.**

Do this even if there are no signs of discomfort or poisoning.

## **5. What should I know while using ZYBAN?**

### **Things you should do**

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ZYBAN.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.**

It may affect other medicines used during surgery.

**If you become pregnant while taking this medicine, tell your doctor immediately.**

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.**

ZYBAN may interfere with some laboratory tests to detect other drugs.

**Keep all of your doctor's appointments so that your progress can be checked.**

### **Things you should not do**

**Do not take ZYBAN to treat any other complaints unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine or lower the dosage without checking with your doctor.**

### **Driving or using machines**

**Be careful driving or operating machinery until you know how ZYBAN affects you.**

This medicine may cause dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

### **Drinking alcohol**

**Be careful when drinking alcohol while you are taking this medicine.**

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.

Some people may find they are more sensitive to alcohol while taking ZYBAN.

Therefore, it is important to discuss your use of alcohol with your doctor before you begin taking ZYBAN.

### **Looking after your medicine**

**Keep your tablets in the original package and in a cool dry place where the temperature stays below 25°C.**

**Do not store ZYBAN or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.**

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### When to discard your medicine

**If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

### Getting rid of any unwanted medicine

If it has expired or is damaged, return it to your pharmacist for disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ZYBAN.**

This medicine helps most people with stopping to smoke, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

#### Fits (seizures)

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 many ZYBAN tablets, if you take some other medicines as well as ZYBAN, or if you are at a higher than usual risk of fits.

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.

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

#### Lupus skin rash or worsening of lupus symptoms

Lupus is an immune system disorder affecting the skin and other organs. Very rarely (up to 1 in 10,000) people may experience lupus skin rash or worsening of lupus symptoms while taking ZYBAN. Symptoms include:

- lupus flares

- skin rash or lesions (particularly on sun-exposed areas)

**If you experience lupus skin rash or worsening of lupus symptoms contact your doctor straight away, as it might be necessary to stop the treatment.**

**Ask your doctor or pharmacist to answer any questions you may have.**

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• difficulty in sleeping</li> <li>• headache, dry mouth</li> <li>• nausea, vomiting</li> <li>• fever, dizziness, sweating, skin rash (sometimes due to an allergic reaction), itching</li> <li>• feeling shaky, feeling weak, chest pain</li> <li>• feeling anxious or agitated, stomach pain, constipation, changes in the taste of food, loss of appetite</li> <li>• increase in blood pressure, flushing</li> <li>• persistent noise in the ears (tinnitus), visual disturbances.</li> <li>• feeling depressed</li> <li>• panic attacks</li> <li>• feeling confused</li> <li>• difficulty concentrating</li> <li>• rapid heart beat</li> <li>• weight loss</li> </ul>	<p><b>Tell your doctor or pharmacist if you notice any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• feeling aggressive, hostile, irritable or restless, strange dreams</li> <li>• hallucinations, feeling unreal or strange (depersonalisation), delusions, paranoia</li> <li>• lupus skin rash or worsening of lupus symptoms</li> <li>• rash with pus filled pimples or blisters</li> <li>• unusual hair loss or thinning (alopecia)</li> <li>• loss of memory</li> <li>• stuttering</li> <li>• twitching, uncontrollable muscle spasms, uncontrolled</li> </ul>	<p><b>Tell your doctor as soon as possible if you notice any of these serious side effects.</b></p>

<p>movements, problems with walking or coordination</p> <ul style="list-style-type: none"> <li>• tingling or numbness</li> <li>• fainting, feeling faint when you stand up suddenly, because your blood pressure falls</li> <li>• fast or irregular heartbeats (palpitations)</li> <li>• urinating more or less than usual</li> <li>• urinary incontinence (involuntary urination, leakage of urine)</li> <li>• your skin or the whites of your eyes turning yellow</li> </ul> <p>Very rare side effects which may show up in blood tests:</p> <ul style="list-style-type: none"> <li>• increase in levels of liver enzymes</li> <li>• changes in blood sugar levels</li> <li>• decrease in blood sodium</li> </ul>	
<ul style="list-style-type: none"> <li>• severe skin rash, itching or hives</li> <li>• swelling of the face, lips, tongue, mouth, throat or eyelids</li> <li>• wheezing, difficulty breathing and swallowing</li> <li>• low blood pressure</li> <li>• pains in muscles or joints</li> <li>• fainting</li> </ul>	<p><b>If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.</b></p>

### Effects of giving up smoking

People giving up smoking are often affected by nicotine withdrawal. This can also affect people taking ZYBAN. Signs of nicotine withdrawal include:

- feeling anxious, agitated
- feelings of depression (sometimes with thoughts of suicide)

**Tell your doctor if you have any concerns about how you feel.**

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects via <https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

### What ZYBAN contains

<b>Active ingredient (main ingredient)</b>	bupropion hydrochloride 150 mg
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• microcrystalline cellulose</li> <li>• hydroxypropyl methylcellulose</li> <li>• cysteine hydrochloride</li> <li>• magnesium stearate</li> <li>• titanium dioxide</li> <li>• carnauba wax</li> <li>• polyethylene glycol</li> <li>• edible black ink</li> </ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

### What ZYBAN looks like

ZYBAN 150 mg tablets are white, biconvex, round, modified release film-coated tablets. The tablets are printed on one side with GX CH7 and plain on the other side. They are available in blister packs of 30 tablets.

### Who distributes ZYBAN

ZYBAN is supplied in New Zealand by:

GlaxoSmithKline NZ Limited

Private Bag 106600

Downtown

Auckland

New Zealand

Ph: (09) 367 2900

Fax: (09) 367 2910

This leaflet was prepared in January 2024.

Version 13.0

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