

ZYBAN

Bupropion hydrochloride 150 mg modified release film-coated tablet

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using ZYBAN.

This leaflet answers some common questions about ZYBAN tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ZYBAN tablets against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

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.

What ZYBAN is used for

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.

Before you take ZYBAN

When you must not take it

Do not take 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.

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.

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.

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

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

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

Before you start to take it

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:

- if you regularly drink a lot of alcohol

- if you regularly take sedatives
- if you have diabetes for which you use insulin or tablets
- if you take stimulants or other medicines to control your weight or appetite
- if you have a brain tumour
- if you have a history of fits
- if you have ever had a serious head injury
- if you 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.

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

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 and ZYBAN may interfere with each other. 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.

How to take 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.

How to take it

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.

When to take it

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 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 take it

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 (overdose)

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.

While you are using ZYBAN

Things you must 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 must 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.

Things to be careful of

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.

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.

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)
- rash with pus filled pimples or blisters.

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.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- difficulty in sleeping
- headache, dry mouth
- nausea, vomiting
- fever, dizziness, sweating, skin rash (sometimes due to an allergic reaction), itching
- feeling shaky, feeling weak, chest pain
- feeling anxious or agitated, stomach pain, constipation, changes in the taste of food, loss of appetite
- increase in blood pressure, flushing
- persistent noise in the ears (tinnitus), visual disturbances.

- feeling depressed
- feeling confused
- difficulty concentrating
- rapid heart beat
- weight loss.

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- feeling aggressive, hostile, irritable or restless, strange dreams
- hallucinations, feeling unreal or strange (depersonalisation), delusions, paranoia
- lupus skin rash or worsening of lupus symptoms
- loss of memory
- stuttering
- twitching, uncontrollable muscle spasms, uncontrolled movements, problems with walking or coordination
- tingling or numbness
- fainting, feeling faint when you stand up suddenly, because your blood pressure falls
- fast or irregular heartbeats (palpitations)
- urinating more or less than usual
- urinary incontinence (involuntary urination, leakage of urine)
- your skin or the whites of your eyes turning yellow.

Very rare side effects which may show up in blood tests:

- increase in levels of liver enzymes
- changes in blood sugar levels
- decrease in blood sodium.

The above list includes serious side effects that may require medical attention. Serious side effects are very rare.

If any of the following happen, tell your doctor immediately or go to

Accident and Emergency at your nearest hospital:

- severe skin rash, itching or hives
- swelling of the face, lips, tongue, mouth, throat or eyelids
- wheezing, difficulty breathing and swallowing
- low blood pressure
- pains in muscles or joints
- fainting.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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 above may also occur in some people.

After using ZYBAN

Storage

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.

Disposal

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.

Product description

What it 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.

Ingredients

ZYBAN tablets contain 150 mg of bupropion hydrochloride as the active ingredient. They also contain:

- microcrystalline cellulose
- hydroxypropyl methylcellulose
- cysteine hydrochloride
- magnesium stearate
- titanium dioxide
- carnauba wax
- polyethylene glycol
- edible black ink.

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

Supplier

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

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