

Zyban(R) Tablets

Bupropion hydrochloride

Consumer Medicine Information

What is in this leaflet?

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

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

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Zyban Tablets against the benefits this medicine is expected to have for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What Zyban Tablets are used for

Zyban tablets contain bupropion hydrochloride. The exact mechanism of action is not fully understood, but it is believed that it interacts with chemicals called noradrenaline and dopamine in the brain.

Zyban is a medicine prescribed by your doctor as a short-term treatment to help you stop smoking with appropriate counselling. For many patients, Zyban reduces withdrawal symptoms and the urge to smoke.

Your doctor may have prescribed Zyban Tablets for another reason.

Ask your doctor if you have any questions about why Zyban Tablets have been prescribed for you.

Zyban Tablets are not addictive.

Before you take Zyban Tablets

You should be fully committed to quitting smoking before you start to take Zyban tablets.

You are more likely to quit smoking if you have appropriate support. You should tell your family, friends and work colleagues that you are trying to quit smoking so that they can offer you support and encouragement.

You must not take Zyban tablets if:

- * **You have ever had an allergic reaction to Zyban, bupropion or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following: wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash ("hives") or fainting.

Allergic reactions can last a long time. Talk to your doctor about the management of the allergic symptoms.

- * **You now have or you have ever had a seizure disorder or 'fit' (eg epilepsy)**

- * **You are usually a heavy drinker but you have suddenly stopped drinking alcohol or you plan to do so while taking Zyban.**
- * **You have suddenly stopped taking tranquillizers or you plan to do so while taking Zyban.**
- * **You have a brain tumour.**
- * **You have ever had an eating disorder (eg. bulimia or anorexia nervosa)**
- * **You are taking a medicine called a Monoamine Oxidase Inhibitor (MAOI), or have taken a Monoamine Oxidase Inhibitor in the last 14 days.**
- * **You are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.**

Your doctor will discuss the risks and benefits of using Zyban tablets if you are pregnant or breastfeeding.

- * **The tablets have passed the expiry date (EXP) printed on the pack.**

If you take it after the expiry date has passed, it may not work as well.

- * **The packaging is torn or shows signs of tampering.**

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 also affected people taking Zyban for smoking cessation.

Bupropion, the active ingredient in Zyban is also used for treatment of depression. People taking anti-depressants sometimes have thoughts of harming or killing themselves. These thoughts may be increased when they first start taking them.

If you feel depressed or think about suicide, get medical advice as soon as possible.

If you're not sure whether you should be taking Zyban tablets, talk to your doctor.

You must tell your doctor if:

- * You are allergic to foods, dyes, preservatives or any other medicines.
- * You are currently taking or have recently taken a monoamine oxidase inhibitor (MAOI)
- * You are currently taking a herbal preparation called St John's Wort
- * You are taking medicines that suppress your appetite
- * You have had a head injury
- * You have liver or kidney problems
- * You have any mental disorder particularly bipolar disorder (also known as manic depression).
- * You suffer from diabetes
- * You had a seizure (fit) while taking a previous course of Zyban
- * You take a lot of medication ('sedatives') to treat anxiety
- * You are a heavy drinker

It is best to not drink alcohol at all or to drink very little while taking Zyban. If you drink a lot of alcohol or suddenly stop, 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.

Taking other medicines

Tell your doctor if you are taking any other medicines (eg. medicines used to treat heart conditions, high blood pressure, psychological illnesses, cancer, depression, epilepsy, Parkinson's disease, muscle relaxants, medicines used to prevent stroke), including medicines you buy without a prescription from a pharmacy, supermarket or health food shop. This includes nicotine patches or nicotine gum.

Some medicines may affect the way others work. It is important not to take medicines that may increase the chance of you having a seizure (fit), for example antimalarials, tramadol (a pain killer), theophylline for asthma, medicines that suppress your appetite, sedating antihistamines, antibiotics belonging to the quinolone class, and steroid tablets and injection. Therefore, you should make sure that your doctor knows about all medicines you are taking or plan to take.

Your doctor or pharmacist will be able to tell you what to do when taking Zyban tablets with other medicines.

Using Zyban and nicotine replacement therapy (ie nicotine patches or nicotine gum) 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.

Use in children

Zyban tablets are not recommended for use in children less than 18 years.

How to take Zyban tablets

The course of Zyban tablets consists of two prescriptions: an initial prescription of 30 tablets followed by a second prescription for 90

tablets.

Your first prescription of 30 tablets will last you approximately 14 days.

It is vital that you obtain the second prescription of 90 tablets and have it ready before you run out of tablets from your first prescription.

Your doctor will tell you how many Zyban tablets to take and how often to take them. You will also find this information on the label of your medicine.

If you do find your sleep disturbed, try not to take Zyban too close to bedtime. If you take two tablets, take one early in the morning and one late in the afternoon. Leave 8 hours between tablets.

How much to take

First prescription

The first prescription for Zyban tablets is for 30 tablets. This represents slightly more than 2 weeks supply of the tablets.

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

You need to visit your doctor for the second prescription of tablets before you run out of tablets from the first prescription.

Second prescription

The second prescription for Zyban tablets is for 90 tablets. This represents slightly more than 6 weeks supply of the tablets.

Take your medicine as your doctor has told you. The usual recommended dose is one 150mg tablet twice daily. Doses should be taken at least 8 hours apart.

Do not take more tablets than your doctor has prescribed. This is important so you do not increase your chance of having a seizure (fits or convulsions).

Your doctor will advise you how to take the tablets if you have liver disease.

How long to take it

It takes about 1 week for Zyban to reach the right levels in your body to be effective. So, to maximise 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 Pharmacist's label on the pack will tell you how to take Zyban tablets. If there is something you do not understand, ask your doctor or pharmacist.

Zyban and nicotine replacement therapy (ie nicotine patches or nicotine gum) should only be used together under the supervision of your doctor.

How to take it

It is important to swallow Zyban tablets whole. Do not chew, divide, or crush tablets - if you do the medicine will be released into your body too quickly. If this happens you may be more likely to get side effects including seizures (fits).

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 take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much Zyban

tablets, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

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

While you are taking Zyban tablets

Things you must do

Tell your doctor or pharmacist that you are taking Zyban tablets if you are about to be started on any new medicines.

Tell your doctor if you become pregnant or are trying to become pregnant.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

You should minimise or avoid drinking alcohol when you are on Zyban treatment.

Things you must not do

Do not stop taking Zyban tablets, or change the dose without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use Zyban tablets to treat any other complaints unless your doctor says to.

Things to be careful of

Be careful driving or operating machinery until you know how Zyban tablets affect you.

As with many other medicines, Zyban tablets may cause dizziness/drowsiness/tiredness/altered concentration/visual disturbance in

some people.

Side-Effects

Check with your doctor as soon as possible if you have any problems while taking Zyban tablets, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Zyban tablets can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

The most commonly reported side-effects are:

- * headache
- * difficulty sleeping (see 'How to take Zyban tablets')
- * dry mouth
- * upset stomach (eg. nausea and constipation)

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

Tell your doctor or pharmacist immediately if you notice any of the following:

- * fever
- * tiredness
- * flushing
- * shakiness
- * anorexia
- * ringing in the ears
- * impaired vision
- * taste disorder
- * loss of appetite
- * changes in mood
- * difficulty in concentrating
- * irritability
- * hostility
- * agitation
- * hallucinations
- * delusions
- * paranoid thoughts
- * anxiety
- * dizziness

- * fluttering of the heart rate
- * tingling or numbness
- * loss of memory
- * changes in blood sugar levels

An increase in blood pressure may be recorded which in some cases can be severe.

If you think you are having an allergic reaction to Zyban tablets, TELL YOUR DOCTOR IMMEDIATELY or go to the casualty department at your nearest hospital. Symptoms usually include some or all of the following:

- * wheezing
- * swelling of the lips/mouth/eyelids
- * difficulty in breathing
- * hay fever
- * lumpy rash ("hives")
- * fainting

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;
- * are taking any other medicine containing bupropion;
- * have had a head injury;
- * are a heavy drinker; or
- * suffer from diabetes.

Other medication may increase the chance of you having a seizure. Refer to the "Taking other medicines" section.

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

This is not a complete list of all

possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Effects of stopping smoking

People giving up smoking are often affected by nicotine withdrawal. Similar effects have also been reported in Zyban users undergoing a smoking cessation attempt. These may include

- * difficulty sleeping, tremor or sweating
- * agitation or feelings of depression (sometimes with thoughts of suicide).

If you feel any worrisome changes of mood, talk to your doctor, immediately.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

After taking Zyban tablets

Storage

Keep this medicine where young children cannot reach it.

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

Keep your Zyban tablets in a cool, dry place where they stay below 25 degrees C.

Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep your Zyban in its pack until it is time to take it.

If you take the Zyban tablets out of the pack they may not keep well.

Disposal

If your doctor tells you to stop taking Zyban tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What Zyban tablets look like.

Zyban tablets are white, film-coated biconvex, round tablets coded 'GX CH7'.

Zyban tablets are supplied in foil blisters. The foil blisters contain 30 and 90 tablets, for oral use only, and they are in a carton.

Ingredients

Zyban tablets contain 150mg of the active ingredient bupropion hydrochloride. They also contain the following inactive ingredients:

Microcrystalline cellulose, hypromellose, cysteine hydrochloride, magnesium stearate, macrogol, titanium dioxide (E171), carnauba wax, edible black ink.

Zyban tablets do not contain lactose.

Zyban Tablets may have a characteristic odour. If present, this odour is normal.

Manufacturer

Your Zyban tablets are supplied by:
 GlaxoSmithKline Australia Pty Ltd
 1061 Mountain Highway
 Boronia
 Victoria, 3155
 Australia.

Further Information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

Do not throw this leaflet away.

You may need to read it again.

This leaflet was prepared on 30 April 2008.

The information provided applies only to Zyban(R) tablets.

(R) Zyban is a registered trade mark of the GlaxoSmithKline Group of Companies.

AUST R 75233

(C) 2003 GlaxoSmithKline

Issue 19