

Zyban® SR tablets

bupropion hydrochloride

Consumer Medicine Information

What is in this leaflet

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

What Zyban SR is used for

Zyban SR tablets contain bupropion hydrochloride as the active ingredient. (This active ingredient is also known as amfebutamone hydrochloride).

It is a medicine prescribed by your doctor as a short-term treatment to help you stop smoking, with appropriate counselling. For many patients, it reduces withdrawal symptoms and the urge to smoke. The exact mechanism of action is not fully understood, but it is believed that it interacts with chemicals in the brain to decrease cravings.

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

Your doctor may have prescribed this medicine for another reason.

Zyban SR tablets are not addictive.

Use in children

This medicine is not recommended for use in children less than 18 years because it has not been adequately studied in these patients.

Before you take it

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

Tell your family, friends and work colleagues that you are trying to quit smoking so that they can offer you support and encouragement.

You are more likely to quit smoking if you have suitable support.

Do not take Zyban SR tablets if:

- **you have ever had an allergic reaction to bupropion or any of the tablet 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.

- **you have or ever had a condition that causes fits or seizures, such as epilepsy**

- **you are usually a heavy drinker and you have just stopped drinking alcohol or you plan to do so while taking Zyban SR**
- **you have recently stopped taking tranquillizers (benzodiazepines) or you plan to do so while taking Zyban SR**
- **you have a brain or spine tumour**
- **you are taking any other medicines which contain bupropion**
- **you have or have had an eating disorder (e.g. bulimia or anorexia nervosa)**
- **you are taking medicines called monoamine oxidase inhibitors (MAOIs) or have taken them 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 taking Zyban SR tablets if you are pregnant, planning a pregnancy or breastfeeding. Some studies have reported an increase in the risk of birth defects, particularly heart defects, in babies whose mothers were taking this medicine. It is not known if these are due to the use of Zyban SR.
- **the tablets have passed the expiry date (EXP) printed on the pack**
- **the packaging is torn or shows signs of tampering.**

Talk to your doctor if you are not sure whether you should be taking Zyban SR tablets.

Before you start to take it

Your doctor needs to know certain information before you start taking this medicine. This is because some conditions make it more likely that you will have side effects. If any of these conditions applies to you, your doctor will monitor you more closely while you are taking Zyban SR tablets or recommend another treatment.

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

- Recent history of heart problems or unstable heart disease
 - Risk of seizures
This medicine has been shown to cause fits (seizures) in some people. Fits are more likely, while taking Zyban SR, 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 appetite or weight
 - have a history of fits
 - have 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 SR. See your doctor for advice.**
- Hypersensitivity reactions
Stop taking this medicine and immediately contact your doctor if you experience an allergic reaction during treatment.
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.
Some allergic reactions can last for quite a long time after exposure to an allergy-causing substance has finished.

- Liver disorders, kidney disorders, elderly patients
You may have more risk of side effects if you have kidney or liver problems, or are elderly.
You may need to take a lower dosage and be checked more closely while you are taking Zyban SR tablets.
Your doctor will advise you.
- 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 also affected people taking Zyban SR for smoking cessation.
If you feel depressed or think about suicide, get medical advice as soon as possible.
- If you have had any mental health problems
Some people taking Zyban SR have had hallucinations or delusions, disordered thoughts or extreme mood swings. These effects are more likely in people who have had mental health problems before, such as bipolar disorder.

Taking other medicines

Tell your doctor if you are allergic to foods, dyes, preservatives or any other medicines.

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

It is important not to take medicines (e.g. antidepressants, antipsychotics, sedating antihistamines) that may increase the chance of you having a fit or seizure.

Speak with your doctor about other medicines you are taking.

Some medicines and substances that may interact with Zyban SR tablets include:

- nicotine skin patches or nicotine gum.
Using this medicine and nicotine replacement therapy (i.e. nicotine patches or nicotine gum) together may raise your blood pressure.
Your doctor may want to check your blood pressure regularly to make sure that it stays within acceptable levels.
- some medicines used to treat heart conditions and high blood pressure, psychological illness (e.g. depression), cancer, epilepsy, Parkinson's disease, some muscle relaxants; medicines used to prevent stroke; some medicines to treat HIV infection (e.g. ritonavir, efavirenz).
- alcohol.
Some people find they are more sensitive to alcohol while taking this medicine. Your doctor may suggest that you don't drink alcohol while you are taking Zyban SR tablets, or that you drink as little as possible.
- a herbal preparation called St. John's Wort.

Tell your doctor or pharmacist if you are taking any of these.

How to take it

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

If you find your sleep disturbed, try not to take this medicine too close to bedtime. If you take two tablets daily, take one early in the morning and one late in the afternoon.

Leave 8 hours between tablets.

How much to take

Do not take more tablets than your doctor has prescribed.

Do not take more than 1 tablet at a time and do not take more than 2 tablets in any one day.

This is important so you do not increase your chance of having significant side effects.

Typically, the first prescription will be for 30 tablets which is slightly more than 2 weeks supply. Treatment will start while you are still smoking with a 'target stop date' set within the first two weeks. A larger pack size of 90 tablets is then usually prescribed for the rest of the treatment. This represents slightly more than 6 weeks supply.

The usual initial recommended dose is one 150 mg tablet each day for the first 3 days, increasing to one tablet twice daily. Doses should be taken at least 8 hours apart.

Take your medicine as recommended by your doctor.

If you have a liver disorder, your doctor will advise you on how many tablets to take as the dosage frequency will be reduced.

How long to take it

To be effective, it takes about one week for the medicine in Zyban SR tablets to reach the right levels in your body.

In order to maximise your chance of stopping, you should not stop smoking until you have been taking Zyban SR for 1 week. You should set a date to stop smoking during the second week.

The usual course of treatment is for at least 7 weeks.

Your doctor will advise you.

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

How to take it

This medicine is intended for oral use only.

Do not chew, divide or crush Zyban SR tablets.

It is important to swallow it whole and not inhale any crushed tablets or inject any dissolved tablets.

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 13 11 26) for advice, if you think you or anyone else may have taken too many Zyban SR tablets, even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking it

Things you must do

Tell your doctor or pharmacist that you are taking Zyban SR 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.

Minimise or avoid drinking alcohol when you are on Zyban SR treatment.

If you require a laboratory test, tell your doctor or hospital that you are taking Zyban SR.

This medicine may interfere with some laboratory tests to detect certain drugs.

Things you must not do

Do not stop taking Zyban SR 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 SR tablets to treat any other complaints unless your doctor says to.

Things to be careful of

Minimise or avoid drinking alcohol when you are on Zyban SR treatment.

If you drink a lot of alcohol or suddenly stop, you may increase your chance of having a seizure. If you are taking sedatives (e.g. benzodiazepines) and stop these abruptly, this can also increase the chance of a seizure. Therefore, it is important to discuss your use of alcohol and medicines with your doctor before you begin taking Zyban SR.

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

As with many other medicines, Zyban SR tablets may cause dizziness or drowsiness in some people.

Side effects

Check with your doctor as soon as possible if you have any problems while taking Zyban SR 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 SR 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.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

The most commonly reported side effects are:

- headache
- difficulty sleeping
- dry mouth
- feeling sick (nausea), being sick (vomiting).

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

- fever
- weakness or lack of energy
- dizziness
- irritability, agitation
- anxiety
- tremor or shakiness
- difficulty in concentrating
- changes in mood
- anorexia
- stomach pain, constipation
- impaired vision
- taste disorders
- rash, itchy skin
- sweating.

An increase in blood pressure may be recorded which in some cases can be severe. Your doctor will monitor this and advise you.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you think you are having an allergic reaction to Zyban SR tablets.

Symptoms can include some or all of the following:

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

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 SR tablets, if you take some other medicines as well as Zyban SR, or if you are at a higher than usual risk of fits (see the 'Risk of seizures' section of this leaflet).

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 SR.

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

Effects of stopping smoking

People giving up smoking are often affected by nicotine withdrawal. Similar effects have also been reported in Zyban SR 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.

Other side effects not listed in this leaflet may also occur in some patients.

After taking it

Storage

Keep this medicine in a cool, dry place where it stays below 25°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 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.

Disposal

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

Product description

What it looks like

Zyban SR tablets are white, film-coated biconvex, round tablets coded 'GX CH7' in black ink on one side. Available in foil blisters in pack sizes of 30 and 90 tablets.

Ingredients

Active ingredient:

Zyban SR tablets contain 150 mg of the active ingredient bupropion hydrochloride.

Inactive ingredients:

- microcrystalline cellulose
- hypromellose
- cysteine hydrochloride
- magnesium stearate
- carnauba wax
- opadry aqueous film coating YS-1-18202-A white
- opadry OY-7300 white
- edible black ink.

Zyban SR tablets do not contain glucose, lactose, tartrazine or any other azo dyes.

Sponsor

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Ltd**

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