



Zyban[®]

150 mg film-coated tablets
Bupropion HCl

Patient information leaflet

This leaflet contains important information about Zyban 150 mg prolonged release film-coated tablets (referred to as Zyban from now on).

It is very important that you read this leaflet carefully before you start taking this medicine to make sure it is right for you.

- Keep the leaflet safe as you may want to read it again.
- If you have any more questions, please ask your doctor or pharmacist.
- Your doctor has prescribed this medicine for YOU. Do not give it to anyone else because it may harm them.

This leaflet contains the following information about Zyban:

1. *What Zyban does*
2. *Before you take Zyban*
3. *Taking Zyban with other medicines*
4. *How to take Zyban*
5. *If you take too many Zyban tablets*
6. *If you miss a dose*
7. *When you should STOP taking Zyban and possible side effects*
8. *Looking after your Zyban tablets*

Zyban contains 150 mg of the active ingredient bupropion hydrochloride, which is released slowly into the body. Zyban also contains the following inactive ingredients: microcrystalline cellulose, hypromellose, cysteine hydrochloride monohydrate, magnesium stearate, macrogol 400, titanium dioxide (E171), carnauba wax and iron oxide black (E172).

Zyban comes in foil blister strips, each containing 10 tablets and is available in a pack of 60 tablets.

Product licence holder and manufacturer

GlaxoSmithKline UK, Stockley Park West, Middlesex UB11 1BT is licensed to sell Zyban in the UK. The tablets are made by Glaxo Wellcome SA, Aranda de Duero (Burgos), Spain.

1. *What Zyban does*

Zyban is a non-nicotine treatment that along with motivational support helps you to give up smoking. Zyban is **not** a nicotine-replacement therapy.

2. *Before you take Zyban*

You should NOT take Zyban if you:

- have ever had an allergic reaction (for example, a rash, itching or shortness of breath) to Zyban, bupropion or any of the other ingredients in Zyban, listed at the beginning of this leaflet
- have ever suffered from any form of epilepsy or have ever had a seizure (also referred to as a fit or convulsion)
- have or have ever had a tumour of the central nervous system (for example, a brain tumour)

- have stopped drinking suddenly after prolonged or heavy drinking
- have suddenly stopped taking tranquilisers or sedative medicines or plan to while taking Zyban
- have ever had an eating disorder (for example, bulimia or anorexia nervosa)
- have severe cirrhosis of the liver (a severe liver disease)
- are currently taking, or have taken in the last 14 days, one of the group of medicines called monoamine oxidase inhibitors (MAOIs), which are normally used to treat depression
- are taking any other medicines which contain bupropion
- have ever suffered from manic depression (bipolar disease)
- are pregnant or likely to become pregnant while taking Zyban

As a **rare** side effect, Zyban can cause seizures (fits or convulsions). **Stop taking Zyban and contact your doctor** if you experience this side effect. Do not take it again.

If you answer 'YES' to any of the following questions, and you have not already discussed the matter with your doctor, you must contact your doctor before taking Zyban. The circumstances below can increase the risk of seizures (fits or convulsions).

- Do you drink heavily (drinking of alcohol during Zyban treatment should be minimised or avoided)?
- Have you ever had an injury to the head?
- Have you got diabetes that needs to be treated with insulin or other medicines?

Again, if you answer 'YES' to any of the following questions, and you have not already discussed the matter with your doctor, you must contact your doctor before taking Zyban.

- Are you breast-feeding?
- Are you under 18?
- Are you elderly?
- Do you have any liver or kidney disease?
- Have you ever suffered from a psychiatric illness?

3. Taking Zyban with other medicines

Before you take Zyban, it is very important to tell your doctor or pharmacist if you are taking any other medicines, either those prescribed by your doctor or those bought without a prescription.

While you are taking Zyban, it is very important to tell your doctor or pharmacist before you take any other **new** medicines, either those prescribed by your doctor or those bought without a prescription.

This is because there are certain medicines, which when taken while you are taking Zyban, can increase the risk of seizures (fits or convulsions). These medicines include:

- Medicines to treat depression (for example, amitriptyline, fluoxetine, paroxetine, desipramine, dothiepin or imipramine) or medicines to treat other psychiatric illness (for example, clozapine, risperidone, thioridazine or olanzapine)
- Anti-malarial medicines (for example, chloroquine or mefloquine)
- Tramadol, which is a strong painkiller
- Theophylline, which is a medicine usually used to treat chest conditions such as asthma or lung disease
- Steroids taken as tablets or injection (for example, prednisolone)
- Some antibiotics belonging to a group called quinolones (for example, ciprofloxacin, nalidixic acid, levofloxacin, norfloxacin or ofloxacin)
- Sedating antihistamines, which are medicines usually used to treat allergic reactions such as hay fever and can make you feel drowsy (for example, chlorpheniramine, diphenhydramine, cyclizine, trimeprazine or promethazine). They can also be used as sleep aids and for travel sickness
- Slimming medicines or other stimulant medicines

Examples of other medicines that you are taking, which may increase the risk of side effects and are particularly important for your doctor or pharmacist to be aware of include:

- Medicines usually used to treat epilepsy (for example, carbamazepine, phenobarbital, phenytoin or valproate)
- Any nicotine-replacement therapy (do not use Zyban and nicotine patches together, unless your doctor has told you to)
- Beta-blockers (for example, metoprolol)
- Medicines to treat abnormal heart rhythm (for example, propafenone or flecainide)

- Medicines to treat Parkinson's Disease (for example, levodopa, amantadine or orphenadrine)
 - Tacrine which is a medicine used to treat Alzheimer's Disease
 - Pentazocine, which is a strong painkiller
 - Cyclophosphamide and ifosfamide, which are medicines mainly used to treat certain cancers
- Zyban can cause dizziness and light-headedness, so it may affect your ability to perform tasks that need judgement, concentration or co-ordination skills. If you are affected in this way, DO NOT drive or operate machinery.

4. How to take Zyban

Zyban is a medicine that is used to help you stop smoking. You should not use it for any other purpose. You should start taking Zyban while you are still smoking (it is not dangerous to smoke and use Zyban at the same time) and set a 'target stop date' for stopping smoking in the second week of treatment (e.g. Day 11). This is because Zyban needs time to start working.

The usual dose for Zyban is:

Take ONE tablet ONCE a day for the first 6 days of your treatment course and then from Day 7, take ONE tablet TWICE a day for the rest of your treatment course.

In some circumstances, for example, if you are taking certain medicines, if you are elderly, or if you have certain kidney or liver conditions, your doctor will tell you to take a lower dose of ONE tablet ONCE a day throughout the whole course.

- Swallow each tablet whole, with a drink of water. Do not crush, suck or chew the tablets
- DO NOT take more than ONE tablet at any one time, and NOT more than TWO tablets in a day. Taking more than the prescribed dose will NOT improve your chances of stopping smoking successfully
- Leave at least 8 hours between each dose
- You may experience difficulty sleeping whilst taking Zyban and this can be reduced by avoiding bedtime dosing (provided that there is at least 8 hours between each dose)
- The treatment course should last between 7 to 9 weeks unless you experience a serious reaction to the medicine (see section 7)
- Drinking of alcohol should be minimised or avoided during treatment as Zyban may increase the effects of alcohol
- Your doctor will ask you to stop taking Zyban if you have not managed to stop smoking for a reasonable length of time by the seventh week of treatment
- Your doctor may decide to reduce your dose gradually when stopping your Zyban treatment
- You should get as much help and support as possible while you are giving up smoking as this will increase your chances of succeeding (see 'Right Time Programme™')
- If you are using any other therapies to help you stop smoking, please ask your doctor or pharmacist for advice

5. If you take too many Zyban tablets

If you take too many Zyban tablets, ask your doctor what to do IMMEDIATELY or contact your nearest accident and emergency department.

6. If you miss a dose

If you forget to take a dose, take your next dose at the usual time. DO NOT take a double dose.

7. When you should STOP taking Zyban and possible side effects

As with all medicines, some people may find that Zyban causes side effects. STOP taking the medicine and tell your doctor IMMEDIATELY if you experience any of the following severe allergy symptoms after taking Zyban. Although they are rare, these symptoms could be serious.

- Sudden wheezing, tightness of the chest or throat, or difficulty breathing
- Swollen eyelids, face, lips, tongue or other part of the body
- Skin rash or blistering of the skin, especially if widespread or if you also get a sore mouth or eyes
- Pain in the muscles or joints
- Collapse or blackout

You should also stop taking Zyban and tell your doctor if you experience skin lumps or 'hives' (like a nettle rash) anywhere on the body, itchiness or fever. These are less serious but happen more often than the symptoms listed above.

As with all medicines, people taking Zyban can experience some side effects.

STOP taking Zyban and tell your doctor IMMEDIATELY should you, during treatment, experience any form of sudden collapse such as a faint, seizure (fit or convulsion) or blackout.

Giving up smoking can cause some effects (withdrawal symptoms) such as agitation, insomnia (difficulty sleeping), tremor and sweating which may be similar to some side effects associated with Zyban and generally occur early during the treatment course.

The more **common** side effects of Zyban that could happen to more than 1 in 100 people taking it include:

- Fever, dry mouth, constipation, tummy discomfort or upset, nausea (feeling of sickness) and vomiting
- Skin rash or itching, including allergy reactions like nettle rash
- Insomnia (difficulty sleeping), agitation, tremor and sweating
- Difficulty concentrating (in rare cases this may include forgetfulness), headache, dizziness, feelings of depression (in rare instances this may include suicidal thoughts), anxiety
- Changes in the taste of food or drink while you are taking Zyban

Uncommon side effects that could happen to between 1 in 100 and 1 in 1,000 people taking Zyban include:

- Chest pain, feeling of weakness
- Faster heartbeat than usual, increased blood pressure, flushing
- Confusion, loss of appetite, ringing in the ears and disturbance of vision

Rare side effects that could happen to between 1 in 1,000 and 1 in 10,000 people taking Zyban include:

- Vasodilation (widening of the blood vessels) and fainting (especially on standing up)
- Irritable or aggressive behaviour
- Seizures (fits or convulsions)
- Tingling or numbness (pins and needles)
- Muscle spasm, tremor and inco-ordination
- Palpitations (irregular or strong heartbeat)
- Hallucinations (seeing, hearing, smelling, tasting or feeling things which are not really there)
- Strange dreams, including nightmares
- Depersonalisation (a feeling of being unreal or strange)
- Severe allergic reactions (as described at the start of this section)
- Jaundice (yellowing of the skin or the eyes) and hepatitis (inflammation of the liver)
- Changes in blood sugar levels
- Worsening of psoriasis
- Urinating more or less than usual (passing water)

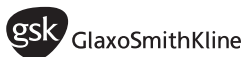
Very Rare side effects that could happen to less than 1 in 10,000 people taking Zyban include:

- Restlessness, aggression, delusions, paranoia

If you experience any of these side effects or any other unusual effects after taking Zyban, you must tell your doctor or pharmacist.

8. Looking after your Zyban tablets

- As with all medicines, it is important to **keep Zyban out of the reach and sight of children.**
- Do not store Zyban above 25°C. Store the tablets in the original pack.
- Do not use Zyban after the expiry date printed on the carton or the foil blister strip.
- If you have any Zyban tablets left after completing your course of treatment, please return them to your pharmacist who will get rid of them safely.



Right TimeTM Programme

*Now you have decided to
stop smoking, what else can you do?*

You need determination and support to stop smoking. Now that you've made that important decision to stop, the 'Right Time Programme' could give you the support you need.

Day by day, the programme gives you practical advice and help.

(see over the page)

To register your interest in the
'Right Time Programme',
fill in the form below and return it to:

Right Time Programme™

FREEPOST GSK1

UXBRIDGE

UB11 1BR

*We will use these details to send you extra information.
We may also use the information to analyse how effective
the programme is.*

Or, you may register by phoning us on
FREEPHONE **0800 169 1313**

The lines are open from
8am to 6pm, Monday to Friday.

Please send me details about the 'Right Time Programme'

Name _____ Address and postcode _____

Signature _____

I smoke _____ cigarettes per day. I have tried to stop _____ times before.

I have tried the following treatments (please tick the appropriate boxes).

Patches Yes No Gum Yes No

Other (please give details) _____

Please tick the ONE main reason why you decided to stop smoking.

A friend or relative has a smoking-related illness Self-esteem

Financial reasons

Health benefits for you Your doctor or nurse recommended that you give up

Health benefits for your family and friends Increased pressure from friends