

## **LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**OUTER CARTON**

**1. NAME OF THE MEDICINAL PRODUCT**

Zyban 150 mg prolonged release film-coated tablets  
Bupropion hydrochloride

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

Each tablet contains 150 mg of bupropion hydrochloride

**3. LIST OF EXCIPIENTS**

**4. PHARMACEUTICAL FORM AND CONTENTS**

30 tablets  
40 tablets  
50 tablets  
60 tablets  
100 tablets

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use

Oral use

Zyban tablets should be swallowed whole and not crushed or chewed.

**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN**

Keep out of the reach and sight of children.

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

**8. EXPIRY DATE**

EXP

**9. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C.

Store in the original package.

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

<[To be completed nationally]>

{Name and Address}

<{tel}>

<{fax}>

<{e-mail}>

**12. MARKETING AUTHORISATION NUMBER(S)**

<[To be completed nationally]>

**13. BATCH NUMBER**

Lot

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

Zyban 150 mg

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**BLISTER FOIL**

**1. NAME OF THE MEDICINAL PRODUCT**

Zyban 150 mg prolonged release tablets

Bupropion HCL

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

GlaxoSmithKline

**3. EXPIRY DATE**

EXP

**4. BATCH NUMBER**

Lot

**5. OTHER**

**PACKAGE LEAFLET**

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Zyban 150 mg prolonged release film-coated tablets

bupropion hydrochloride

**Read all of this leaflet carefully before you start using this medicine.**

**Keep this leaflet. You may need to read it again.**

If you have more questions, ask your doctor or your pharmacist.

This medicine has been prescribed for you. Don't pass it on to others. It may harm them, even if their symptoms are the same as yours.

**If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

**In this leaflet**

- 1 What Zyban is and what it is used for**
- 2 Before you take Zyban**
- 3 How to take Zyban**
- 4 Possible side effects**
- 5 How to store Zyban**
- 6 Further information**

#### **1 WHAT ZYBAN IS AND WHAT IT IS USED FOR**

Zyban is a medicine prescribed to help you stop smoking, when you also have motivational support such as taking part in a 'stop smoking' programme.

**Zyban will be most effective if you are fully committed to giving up smoking.** Ask your doctor or pharmacist for advice on treatments and other support to help you stop..

#### **2 BEFORE YOU TAKE ZYBAN**

**Don't take Zyban**

- **if you are allergic** (*hypersensitive*) to bupropion (the active substance), or any of the other ingredients in Zyban tablets (*listed in Section 6*)
- **if you are taking any other medicines which contain bupropion** (such as [**Tradenam**], to treat depression)
- **if you have a condition that causes fits** (*seizures*), such as **epilepsy**, or if you have a history of fits
- **if you have an eating disorder**, or had one in the past (for example, bulimia or anorexia nervosa)
- **if you have severe liver problems**, such as *cirrhosis*
- **if you have a 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 or medicines to treat anxiety** (especially *benzodiazepines* or similar medicines), or if you are going to stop them while you're taking Zyban
  - **if you have a bipolar disorder** (extreme mood swings), as Zyban could bring on an episode of this illness
  - **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. The timing may be shorter for some types of MAOIs, your doctor will advise you.
- ➔ **If any of these applies to you, talk to your doctor straight away, and don't take Zyban.**

### Take special care with Zyban

**Your doctor needs to know certain information before you start taking Zyban.** This is because some conditions make it more likely that you will have side effects (*see also Section 4*).

#### Fits (*seizures*)

Zyban has been shown to cause fits (seizures) in about 1 in 1000 people. (*See also 'Taking other medicines' later in this section and Section 4, 'Possible side effects', for more information*). Fits are more likely:

- **if you regularly drink a lot of alcohol**
- **if you have diabetes** for which you use insulin or tablets
- **if you have had a serious head injury** or a history of head trauma

If any of these applies to you, don't take Zyban unless you have agreed with your doctor that there is a strong reason for doing so.

If you have a fit (seizure) during treatment:

➔ **Stop taking Zyban and don't take any more. See your doctor.**

#### You may have more risk of side effects:

- **if you have kidney or liver problems**
- **if you are aged over 65**

You will need to take a lower dose (*see Section 3*) and be checked closely while you are taking Zyban.

#### If you have had any mental health problems...

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

#### 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 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 a hospital straight away.**

#### High blood pressure and Zyban...

Some people taking Zyban have developed high blood pressure which needs treatment. If you already have high blood pressure, it can become worse. This is more likely if you are also using **nicotine patches** to help you stop smoking.

**You will have your blood pressure checked** before you take Zyban and while you are taking it, especially if you already have high blood pressure. If you are also using nicotine patches, your blood

pressure needs to be checked every week. If your blood pressure increases, you may need to stop taking Zyban.

### **Taking other medicines**

**Tell your doctor or pharmacist if you're taking any other medicines, if you've taken any recently, or if you start taking new ones**, including medicines you bought without a prescription.

**There may be a higher than usual risk of fits if you take:**

- medicines for **depression** or **other mental health problems** (*see also 'Don't take Zyban' at the beginning of Section 2*)
  - **theophylline** for **asthma** or **lung disease**
  - **tramadol**, a strong painkiller
  - medicines against **malaria**
  - **stimulants** or other medicines to control your **weight or appetite**
  - **steroids** (except creams and lotions for eye and skin conditions)
  - **antibiotics** called **quinolones**
  - **some types of anti-histamines** mainly used to treat allergies, that can cause sleepiness
  - medicines for **diabetes**.
- ➔ **If you take any medicines in this list, talk to your doctor straight away**, before you take Zyban (*see section 3 under 'Some people need to take a lower dose'*).

**Some medicines can affect how Zyban works, or make it more likely that you'll have side effects. Zyban can also affect how some other medicines work. These include:**

- medicines for **depression** (such as desipramine, imipramine, paroxetine) or **other mental health problems** (such as risperidone, thioridazine)
  - medicines for **Parkinson's disease** (such as levodopa, amantadine or orphenadrine)
  - **carbamazepine, phenytoin** or **valproate**, to treat **epilepsy** or some **mental health problems**
  - some medicines used to treat **cancer** (such as cyclophosphamide, ifosfamide)
  - **ticlopidine** or **clopidogrel**, mainly used to treat **heart disease** or **stroke**
  - some **beta blockers** (such as metoprolol), mainly used to treat high blood pressure
  - some medicines for **irregular heart rhythm** (such as propafenone, flecainide)
  - **ritonavir** or **efavirenz**, for treatment of HIV infection.
- ➔ **If you take any medicines on this list, check with your doctor.** Your doctor will weigh up the benefits and risks to you of taking Zyban, or may decide to change the dose of the other medicine you are taking.

### **The dose of some medicines may need to be reduced when you stop smoking**

When you smoke, the chemicals absorbed into your body can cause some medicines to be less effective. When you stop smoking, your dose of these medicines may need to be reduced; otherwise, you may get side effects.

If you are taking any other medicines, check with your doctor if you notice any new symptoms that you think may be side effects.

### **Alcoholic drink and Zyban**

Some people find they are more sensitive to alcohol while taking Zyban. Your doctor may suggest you do not drink alcohol while you're taking Zyban, or try to drink as little as possible. If you do drink a lot now, don't just stop suddenly, because that may put you at risk of having a fit.

### **Pregnancy and breast feeding**

**Don't take Zyban if you are pregnant or planning to become pregnant.** Ask your doctor or pharmacist for advice before taking any medicine while pregnant.

The ingredients of Zyban can pass into breast milk. You should ask your doctor or pharmacist for advice before taking Zyban.

### **Driving and using machines**

Some of the side effects of Zyban, such as feeling dizzy or light-headed, may affect your concentration and judgement.

**If you are affected, don't drive or operate machinery.**

## **3 HOW TO TAKE ZYBAN**

**Always take Zyban exactly as your doctor has advised you.** Check with your doctor or pharmacist if you are unsure.

Zyban is not recommended for people under 18 years.

<b>When to start and how much to take</b>		
<ul style="list-style-type: none"><li>• <b>Start taking Zyban while you are still smoking.</b></li><li>• <b>Set a Target Stop Smoking Day ideally during the second week you're taking it.</b></li></ul>		
<b>Week 1</b> <b>Ideally keep smoking while taking Zyban</b>	<b>Days 1 to 6</b>	Take <b>one tablet (150 mg), once a day.</b>
	<b>Day 7</b>	Increase your dose to <b>one tablet, twice a day</b> , at least 8 hours apart, and <b>not near to bedtime.</b>
<b>Week 2</b>	Carry on taking <b>one tablet, twice a day.</b> Stop smoking this week, on your <b>Target Stop Smoking Day.</b>	
<b>Weeks 3 to 9</b>	Carry on taking <b>one tablet, twice a day for up to 9 weeks.</b> If you have not been able to stop smoking after <b>7 weeks</b> , your doctor will advise you to stop taking Zyban. You may be advised to stop taking Zyban gradually, after 7–9 weeks.	

### **Some people need to take a lower dose**

... as they may be more likely to get side effects.

- if you are aged over 65
- if you have liver or kidney disease
- if you have a higher risk of fits (*see 'Take special care with Zyban' and 'Taking other medicines' in Section 2*)

the maximum recommended dose for you is **one 150 mg tablet once a day.**

### **How to take your tablets**

**Take your Zyban tablets at least 8 hours apart. Don't take Zyban near to bedtime** — it may cause difficulty in sleeping.

You can take Zyban with or without food.

**Swallow your Zyban tablets whole.** Don't chew them, crush them or split them — if you do, the medicine will be released into your body too quickly. This will make you more likely to have side effects, including fits.



#### **If you take more Zyban than you should**

If you take too many tablets, you may be more likely to have a fit or other side effects.

➔ **Don't delay.** Contact your doctor or your nearest hospital emergency department immediately.

#### **If you forget to take Zyban**

If you miss a dose, wait and take your next tablet at the usual time.

**Don't take an extra tablet to make up** for the dose you forgot.

#### **If you stop taking Zyban**

You may need to take Zyban for as long as 7 weeks to have its full effect.

**Don't stop taking Zyban without talking to your doctor first.** You may need to reduce your dose gradually.

If you have any further questions about using Zyban, ask your doctor or pharmacist.

## **4 POSSIBLE SIDE EFFECTS**

Like all medicines, Zyban can cause side effects, although not everyone gets them.

### ***Fits (seizures)***

Approximately 1 in every 1,000 people taking Zyban is at risk of having a fit.

**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 much, if you take some other medicines, or if you are at higher than usual risk of fits (*see Section 2*).

➔ **If you have a fit,** tell your doctor when you have recovered. **Don't take any more Zyban.**

### **Allergic reactions**

Rarely (up to 1 in 1000) people may have potentially serious allergic reactions to Zyban. Signs of allergic reactions include:

- skin rash (including itchy, bumpy rash). Some skin rashes may need hospital treatment, especially if you also have a sore mouth or sore eyes.
- unusual wheezing, or difficulty in breathing
- swollen eyelids, lips or tongue
- pains in muscles or joints
- collapse or blackout.

➔ **If you have any signs of an allergic reaction, contact a doctor at once. Don't take any more tablets.**

### **Very common side effects**

These may affect **more than one in 10** people:

- difficulty in sleeping (make sure you don't take Zyban near to bedtime).

### **Common side effects**

These may affect **up to one in 10** people:

- feeling depressed (*see also 'Take special care with Zyban' in Section 2*)
- feeling anxious or agitated
- difficulty concentrating
- feeling shaky (tremor)
- headache
- feeling sick (nausea), being sick (vomiting)
- stomach pain or other upsets (such as constipation), changes in the taste of food, dry mouth
- fever, dizziness, sweating, skin rash (sometimes due to an allergic reaction), itching.

### **Uncommon side effects**

These may affect **up to one in 100** people:

- ringing in the ears, visual disturbances
- increase in blood pressure (sometimes severe), flushing
- loss of appetite (*anorexia*)
- feeling weak
- chest pain
- feeling confused
- rapid heartbeat.

### **Rare side effects**

These may affect **up to one in 1,000** people:

- fits (see the beginning of this section)
- twitching, muscle stiffness, uncontrolled movements, problems with walking or coordination (*ataxia*)
- palpitations
- fainting, feeling faint when you stand up suddenly, because your blood pressure falls
- feeling irritable or hostile; strange dreams (including nightmares)
- loss of memory
- tingling or numbness
- severe allergic reactions; rash together with joint and muscle pains (*see the beginning of this section*)
- urinating (passing water) more or less than usual
- severe skin rashes that may affect the mouth and other parts of the body and can be life-threatening
- worsening of psoriasis (thickened patches of red skin)
- your skin or the whites of your eyes turning yellow (jaundice), increase in liver enzymes, hepatitis
  
- changes in blood sugar levels
- feeling unreal or strange (*depersonalisation*); seeing or hearing things that are not there (*hallucinations*).

### **Very rare side effects**

These may affect **up to one in 10,000** people:

- feeling restless, aggressive

- sensing or believing things that are not true (*delusions*); severe suspiciousness (*paranoia*).

### **Other side effects**

Other side effects have occurred in a small number of people but their exact frequency is unknown:

- thoughts of harming or killing themselves while taking Zyban or soon after stopping treatment (see Section 2, *Before you take Zyban*). If you have these thoughts, **contact your doctor or go to a hospital straight away**
- loss of contact with reality and unable to think or judge clearly (*psychosis*); other symptoms may include hallucinations and/or delusions.

### **Effects of giving up smoking**

People who stop smoking are often affected by nicotine withdrawal. This can also affect people taking Zyban. Signs of nicotine withdrawal include:

- difficulty in sleeping
- tremor or sweating
- feeling anxious, agitated or depressed, sometimes with thoughts of suicide.

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

### **If you get side effects**

- ➔ **Tell your doctor or pharmacist** if any of the side effects becomes severe or troublesome, or if you notice any side effects not listed in this leaflet.

## **5 HOW TO STORE ZYBAN**

**Keep out of the reach and sight of children.**

Do not use Zyban after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Do not store Zyban above 25 °C.

Store it in the original package.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6 FURTHER INFORMATION**

### **What Zyban contains**

Each tablet contains 150 mg of the active substance, bupropion hydrochloride.

The other ingredients are: Tablet core: microcrystalline cellulose, hypromellose, cysteine hydrochloride monohydrate, magnesium stearate. Tablet coating: hypromellose, macrogol 400, titanium dioxide (E171), carnauba wax. Printing ink: hypromellose, iron oxide Black (E172).

### **What Zyban looks like and contents of the pack**

Zyban 150 mg tablets are white, film-coated, biconvex, round tablets imprinted with “GX CH7” on one side. They are available in cartons containing blisters of 30, 40, 50, 60, or 100 tablets.

Not all listed pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder** <[To be completed nationally]>

{Name and address }

<{tel}>

<{fax}>

<{e-mail}>

#### **Manufacturer**

Glaxo Wellcome SA, Avenida de Extremadura, 3, 09400 Aranda de Duero, Burgos, Spain.

**This medicinal product is authorised in the Member States of the EEA under the following names:**

**Zyban:** Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Norway, Portugal, Sweden, The Netherlands, UK

**Quomem:** Austria, Spain, The Netherlands

**Zyntabac:** Spain, The Netherlands

**Geronplase:** Spain

**This leaflet was last approved in {MM/YYYY}**

<[To be completed nationally]>

**End of MRP procedure: 5 November 2010**