

LABELLING

PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGING

CARTON AND BOTTLE LABEL

1. NAME OF THE MEDICINAL PRODUCT

Wellbutrin XR 150 mg Modified Release 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

7 modified release tablets
30 modified release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use
Oral use
Once Daily
Wellbutrin XR 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 {MM YYYY}

9. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from moisture and light.

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

Not applicable

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

12. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

13. BATCH NUMBER

lot {XXXXXX}

14. GENERAL CLASSIFICATION FOR SUPPLY

<[To be completed nationally]>

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Wellbutrin XR 150 mg

PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGING

CARTON AND BOTTLE LABEL

1. NAME OF THE MEDICINAL PRODUCT

Wellbutrin XR 300 mg Modified Release tablets
Bupropion hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 300 mg of bupropion hydrochloride

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

7 modified release tablets
30 modified release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use
Oral use
Once Daily
Wellbutrin XR 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 {MM YYYY}

9. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from moisture and light.

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

Not applicable

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

12. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

13. BATCH NUMBER

lot {XXXXXX}

14. GENERAL CLASSIFICATION FOR SUPPLY

<[To be completed nationally]>

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Wellbutrin XR 300 mg

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

WELLBUTRIN XR 150 mg modified release tablets WELLBUTRIN XR 300 mg modified release 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 your 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 WELLBUTRIN XR is and what it is used for
2. Before you take WELLBUTRIN XR
3. How to take WELLBUTRIN XR
4. Possible side effects
5. How to store WELLBUTRIN XR
6. Further information

1. WHAT WELLBUTRIN XR IS AND WHAT IT IS USED FOR

WELLBUTRIN XR is a medicine prescribed by your doctor to treat your depression. It's thought to interact with chemicals in the brain called *noradrenaline* and *dopamine*, which are linked with depression.

2. BEFORE YOU TAKE WELLBUTRIN XR

Do not take WELLBUTRIN XR

- **If you know that you are allergic** to WELLBUTRIN XR, bupropion, or any of the other ingredients in WELLBUTRIN XR tablets
- **If you are taking any other medicines which contain bupropion**
- **If you have been diagnosed with epilepsy or have a history of seizures.**
- **If you have an eating disorder**, or used to (for example, bulimia or anorexia nervosa)
- **If you have a brain tumour**
- **If you are usually a heavy drinker** who has just stopped or are about to stop drinking
- **If you have severe liver problems**
- **If you recently stopped taking sedatives**, or if you are going to stop them while you're taking WELLBUTRIN XR
- **If you are taking or have been taking other medicines for depression** called *monoamine oxidase inhibitors* (MAOIs) in the last 14 days

If any of these applies to you, talk to your doctor straight away, **without taking WELLBUTRIN XR.**

Take special care with WELLBUTRIN XR

Use in children under 18 years of age

WELLBUTRIN XR is not recommended to treat children under 18 years of age.

There is an increased risk of suicidal thoughts and behaviour when children under 18 years of age are treated with antidepressants.

Your doctor needs to know before you take WELLBUTRIN XR:

- **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**

WELLBUTRIN XR has been shown to cause fits (seizures) in about 1 in a 1000 people. This side effect is more likely to occur in people from the groups listed above. If you have a fit during treatment you should stop taking WELLBUTRIN XR. **Do not take any more and see your doctor.**

- **If you have a bipolar disorder** (extreme mood swings), as WELLBUTRIN XR could bring on an episode of this illness.
- **If you have liver or kidney problems**, you may be more likely to get side effects.

If any of the above apply to you, talk to your doctor again before taking WELLBUTRIN XR. He or she may want to pay special attention to your care, or recommend another treatment.

Thoughts of suicide and worsening of your depression

If you are depressed you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

You may find it helpful to tell a relative or close friend that you are depressed, and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

Taking other medicines

If you are taking or have taken other antidepressants called *monoamine oxidase inhibitors* (MAOIs) in the last 14 days, **tell your doctor without taking WELLBUTRIN XR** (see also ***Do not take WELLBUTRIN XR*** in Section 2).

If you are taking any other medicines, herbs or vitamins, including products you bought yourself, **tell your doctor**. He or she may alter your dose of WELLBUTRIN XR, or suggest a change in your other medications.

Some medicines don't mix with WELLBUTRIN XR. Some of them may increase the chance of fits or seizures. Other medicines may increase the risk of other side effects. Some examples are listed below, but it is not a complete list.

There may be a higher than usual chance of seizures...

- **If you take other medicines for depression or other mental illness**
- **If you take theophylline** for asthma or lung disease
- **If you take tramadol**, a strong painkiller
- **If you have been taking sedatives**, or if you are going to stop them while you're taking WELLBUTRIN XR (see also *Do not take WELLBUTRIN XR* in Section 2).
- **If you take medicines against malaria** (such as mefloquine or chloroquine)
- **If you take stimulants or other medicines to control your weight or appetite**
- **If you take steroids (by mouth or injection)**
- **If you take antibiotics called quinolones**
- **If you take some types of anti-histamines that can cause sleepiness**
- **If you take medicines for diabetes**

If any of these applies to you, talk to your doctor straight away, before taking WELLBUTRIN XR. Your doctor will weigh up the benefits and risks to you of taking WELLBUTRIN XR.

There may be a higher than usual chance of other side effects...

- **If you take other medicines for depression** (such as amitriptyline, fluoxetine, paroxetine, dosulepin, desipramine or imipramine) or other mental illness (such as clozapine, risperidone, thioridazine or olanzapine).
- **If you take medicines for Parkinson's disease** (levodopa, amantadine or orphenadrine)
- **If you take medicines that affect your body's ability to breakdown WELLBUTRIN XR** (carbamazepine, phenytoin, valproate)
- **If you take cyclophosphamide or ifosfamide, mainly used to treat cancer**
- **If you take ticlopidine or clopidogrel, mainly used to prevent stroke**
- **If you take some beta blockers** (such as metoprolol)
- **If you take some medicines for irregular heart rhythm** (propafenone or flecainide)
- **If you use nicotine patches to help you stop smoking.**

If any of these applies to you, talk to your doctor straight away, before taking WELLBUTRIN XR.

WELLBUTRIN XR may be less effective

- **If you take ritonavir or efavirenz**, medicines to treat HIV infection.

If this applies to you, tell your doctor. Your doctor will check how well WELLBUTRIN XR is working for you. It may be necessary to increase your dose or change to another treatment for your depression. **Do not increase** your WELLBUTRIN XR dose without advice from your doctor, as this may increase the risk of you having side effects, including seizures.

Alcoholic drink and WELLBUTRIN XR

Alcohol can affect the way WELLBUTRIN XR works and, when used together can rarely affect your nerves or your mental state. Some people find they are more sensitive to alcohol when taking WELLBUTRIN XR. Your doctor may suggest you do not drink alcohol (beer, wine or spirits) while taking WELLBUTRIN XR, or try to drink very little. But if you drink a lot now, do not stop suddenly: it may put you at risk of having a fit.

Talk to the doctor about drinking before you start taking WELLBUTRIN XR.

Pregnancy and breast-feeding

Do not take WELLBUTRIN XR if you are pregnant unless your doctor recommends it. Ask your doctor or pharmacist for advice before taking any medicine while pregnant.

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

Driving and using machines

If WELLBUTRIN XR makes you dizzy or light-headed, do not drive or operate any tools or machines.

3. HOW TO TAKE WELLBUTRIN XR

Always take WELLBUTRIN XR exactly as your doctor has advised you. These are the usual doses, but your doctor's advice is personal to you. You should check with your doctor or pharmacist if you are unsure.

It may take a while before you start feeling better. It takes time for the medicine to have its full effect, sometimes weeks or months. When you do start feeling better, your doctor may advise you to keep taking WELLBUTRIN XR to prevent depression coming back.

How much to take

The usual recommended dose for adults only is **one** 150mg tablet every day.

Your doctor may increase your dose to 300 mg every day if your depression does not improve after several weeks.

Take your dose of WELLBUTRIN XR tablets in the morning. Do not take WELLBUTRIN XR more than once each day.

Swallow your tablets whole. Do not chew them, crush them or split them — if you do, there is a danger you could overdose, because the medicine will be released into your body too quickly. This will make you more likely to have side effects, including fits (seizures).

Some people will stay on one 150mg tablet every day for the whole of their treatment. Your doctor may have prescribed this if you have liver or kidney problems.

How long to take it for

Only you and your doctor can decide how long you should take WELLBUTRIN XR. It may take weeks or months of treatment for you to see any improvement. Discuss your symptoms with your doctor regularly to decide how long you should be taking it. When you do start feeling better your doctor may advise you to keep taking WELLBUTRIN XR to prevent depression coming back.

If you take more WELLBUTRIN XR than you should

If you take too many tablets, you may increase the risk of a fit or seizure. **Don't delay.** Ask your doctor what to do or contact your nearest hospital emergency department at once.

If you forget to take WELLBUTRIN XR

If you miss a dose, wait and take your next tablet at the usual time. **Do not take a tablet to catch up** for the dose you forgot.

If you stop taking WELLBUTRIN XR

Do **not** stop taking WELLBUTRIN XR or reduce your dose without talking to your doctor first.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Fits or seizures

Approximately 1 in every 1000 people taking WELLBUTRIN XR is at risk of a fit (a seizure or convulsion). The chance of this happening is higher if you take too much, if you take certain medicines, or if you are at higher than usual risk of fits. If you are worried, talk to your doctor.

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

Allergic reactions

Some people may get allergic reactions to WELLBUTRIN XR. These include

- Red skin or rash (like nettle rash), blisters or itchy lumps (hives) on the skin. 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.**

Allergic reactions can last a long time. If your doctor prescribes something to help with allergic symptoms, make sure you finish the course.

Other side effects

Very common side effects: these may affect more than one in 10 people

- Difficulty in sleeping. Make sure you take WELLBUTRIN XR in the morning
- Headache
- Dry mouth
- Feeling sick, vomiting

Common side effects: these may affect up to one in 10 people

- Fever, dizziness, itching, sweating and skin rash (sometimes due to an allergic reaction)
- Shakiness, tremor, weakness, tiredness, chest pain
- Feeling anxious or agitated
- Tummy pain or other upsets (constipation), changes in the taste of food, loss of appetite (anorexia)
- Increase in blood pressure sometimes severe, flushing
- Ringing in the ears, visual disturbances

Uncommon side effects may affect up to one in 100 people

- Feeling depressed (see also section 2 **Take special care with WELLBUTRIN XR**, under **Thoughts of suicide and worsening of your depression**)

- Feeling confused
- Difficulty concentrating
- Raised heart rate
- Weight loss

Rare side effects may affect up to one in 1,000 people

- Seizures

Very Rare side effects may affect up to one in 10,000 people

- Palpitations, fainting
- Twitching, muscle stiffness, uncontrolled movements, problems with walking or coordination
- Feeling restless, irritable, hostile, aggressive, strange dreams, tingling or numbness, loss of memory
- Yellowing of skin or the whites of your eyes (*jaundice*) which may be caused by raised liver enzymes, hepatitis
- Severe allergic reactions; rash together with joint and muscle pains.
- Changes in blood sugar levels
- Urinating 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)
- feeling unreal or strange (*depersonalisation*); seeing or hearing things that are not there (*hallucinations*); 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 Wellbutrin XR or soon after stopping treatment (see Section 2, *Before you take Wellbutrin XR*). 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.

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

5. HOW TO STORE WELLBUTRIN XR

Keep out of the reach and sight of children.

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

Store it in the original pack in order to protect from moisture and light. The bottle contains a small sealed canister containing charcoal and silica gel to keep the tablets dry. Keep the canister in the bottle. Do not swallow it.

Medicines should not be disposed of via wastewater 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 WELLBUTRIN XR contains

The active substance is bupropion hydrochloride. Each tablet contains 150 mg or 300 mg of bupropion hydrochloride.

The other ingredients are: tablet core: polyvinyl alcohol, glyceryl dibehenate, tablet coating: ethyl cellulose, povidone K-90, macrogol 1450, methacrylic acid ethyl acrylate copolymer dispersion, silicon dioxide, triethyl citrate.

Printing ink: Shellac Glaze, Iron Oxide Black (E172), and Ammonium Hydroxide.

What WELLBUTRIN XR looks like and contents of the pack

WELLBUTRIN XR 150 mg tablets are creamy white to pale yellow round tablets imprinted with "GS5FV" in black ink on one side and the other side plain. They are available in white polyethylene bottles of 7, 30 or 90 (3X30) tablets.

WELLBUTRIN XR 300 mg tablets are creamy white to pale yellow round tablets imprinted with "GS5YZ" in black ink on one side and the other side plain. They are available in white polyethylene bottles of 7, 30 or 90 (3X30) tablets.

Marketing Authorisation Holder and Manufacturer

Manufacturer of WELLBUTRIN XR is Glaxo Wellcome GmbH & Co. KG
Industriestrasse 32-36, 23843 Bad Oldesloe, GERMANY

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

Wellbutrin XR: Austria, Belgium, Luxembourg, Cyprus, Greece, Italy, Malta, Poland, Portugal, Slovenia, Switzerland, The Netherlands.

Elontril: Austria, Czech Republic, Estonia, Germany, Hungary, Iceland, Italy, Latvia, Lithuania, Portugal, Romania, Slovakia, Spain, The Netherlands

Magerion: Germany and Sweden

Wellbutrin Retard: Norway

Voxra: Finland, Sweden.

This leaflet was last approved in {MM/YYYY}

[To be completed nationally]

End of MRP procedure: 5 November 2010