Patient Information Leaflet

SCHEDULING STATUS: S5

WELLBUTRIN XL 150 extended-release tablets

WELLBUTRIN XL 300 extended-release tablets

Bupropion hydrochloride

Sugar-free

Read all of this leaflet carefully before you start taking WELLBUTRIN XL.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- WELLBUTRIN XL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist, nurse or other healthcare provider. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What WELLBUTRIN XL is and what it is used for
2. What you need to know before you take WELLBUTRIN XL
3. How to take WELLBUTRIN XL
4. Possible side effects

5. How to store WELLBUTRIN XL

6. Contents of the pack and other information.

1. What WELLBUTRIN XL is and what it is used for:

- WELLBUTRIN XL 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.
- **It may take a while before you start feeling better**. It takes time for WELLBUTRIN XL to have its full effect, sometimes weeks or months**.** When you do start feeling better, your doctor may advise you to keep taking WELLBUTRIN XL to prevent depression coming back.
- **Your doctor has chosen this medicine to suit you and your condition.** Don't pass it on to others. Before deciding on treatment with WELLBUTRIN XL, you and your doctor will probably have discussed the risks of harm and the benefits that it is likely to have for you. This leaflet will help you to take WELLBUTRIN XL safely.

2. What you need to know before you take WELLBUTRIN XL:

Do not take WELLBUTRIN XL:

- if you know that you are allergic to WELLBUTRIN XL, bupropion, or any of the other ingredients in WELLBUTRIN XL tablets (listed in section 6)
- if you are taking any other medicines which contain bupropion
- if you have been diagnosed with epilepsy
- if you have a brain tumour
- if you have an eating disorder**,** or used to (e.g., bulimia or anorexia nervosa)

- if you are usually a heavy drinker who has just stopped or are about to stop drinking
- if you recently stopped taking tranquillisers or sedatives, or if you are going to stop them while you're taking WELLBUTRIN XL
- if you have been taking other medicines for depression called monoamine oxidase inhibitors (MAOIs) in the last 14 days
- if you are younger than 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
- If any of these applies to you, talk to your doctor straight away, without taking WELLBUTRIN XL.
- If you are a woman of child-bearing potential and not using contraception.

Warnings and precautions:

Talk to your doctor or healthcare provider before taking WELLBUTRIN XL:

- if you've ever had any fits or seizures in the past
- if you have a brain tumour
- if you have liver or kidney problems
- if you regularly drink a lot of alcohol
- if you have diabetes for which you use insulin or tablets
- if you have had any mental illness other than depression
- if you have had a serious head injury
- if you are over 65 years of age
- if you are pregnant or plan to become pregnant soon
- If you suffer from high blood pressure

- Cardiac conduction disorders (Brugada syndrome)-if you have a condition called Brugada syndrome (a rare hereditary syndrome that affects the heart rhythm) or if cardiac arrest or sudden death occurred in your family.

If any of the above applies to you, your doctor may want to pay special attention to your care or recommend another treatment.

Thoughts of suicide or worsening of your condition:

If you are depressed, you can sometimes have thoughts of harming or killing yourself. These thoughts may be increased when first starting antidepressants. 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 under 25 years old.

If you have thoughts of harming or killing yourself at any time: Get medical advice as soon as possible (from a doctor or at a hospital).

Other medicines and WELLBUTRIN XL:

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

If you have been taking other medicines for depression called monoamine oxidase inhibitors (MAOIs) in the last 14 days, tell your doctor without taking WELLBUTRIN XL.

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 XL or suggest a change in your other medications.

Some medicines don't mix with WELLBUTRIN XL. Some of them may increase the chance of seizures (fits). Other medicines may increase the risk of other side effects. Some examples are listed below, but it is not an exhaustive list.

There may be a higher than usual chance of seizures (fits):

- if you take medicines which make seizures (fits) more likely e.g., theophylline for asthma or lung disease, tramadol (a strong painkiller)
- if you have been taking tranquillisers or sedatives, or if you are going to stop them while you're taking WELLBUTRIN XL
- if you take stimulants or other medicines to control your weight or appetite.

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

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

- if you take certain other medicines for depression or other mental illness (such as desipramine or selective serotonin reuptake inhibitors (SSRIs)),
- if you take medicines for Parkinson's disease (levodopa, amantadine or orphenadrine)
- if you take medicines used for epilepsy (carbamazepine, phenytoin, phenobarbitone)
- 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
- if you take medicines for heart rhythm
- 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 XL.

WELLBUTRIN XL may make other medicines less effective:

If you take digoxin for your heart, tell your doctor. Your doctor may consider adjusting the dose of digoxin.

Laboratory tests:

WELLBUTRIN XL may interfere with some urine tests to detect other medicines or substances. If you require a urine test, tell your doctor that you are taking WELLBUTRIN XL.

WELLBUTRIN XL with food, drink and alcohol:

Some people find they are more sensitive to alcohol when taking WELLBUTRIN XL and your doctor may suggest you do not drink alcohol (beer, wine or spirits) while taking WELLBUTRIN XL, or try to drink very little. But if you drink a lot now, do not stop suddenly: it may be risky. Talk to the doctor about drinking before you start taking WELLBUTRIN XL.

Pregnancy and breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking WELLBUTRIN XL.

You should not take WELLBUTRIN XL when you are pregnant.
Studies have reported an increase in the risk of birth defects, particularly heart defects, in babies whose mothers were taking WELLBUTRIN XL.
If you are a woman of child-bearing potential, you should use reliable contraception.
Mothers on WELLBUTRIN XL should not breastfeed their babies.

Driving and using machines:

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

3. How to take WELLBUTRIN XL:

Do not share medicines prescribed for you with any other person.
Always take WELLBUTRIN XL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How much to take:

The usual starting dose for adults is one 150 mg tablet every day.
Your doctor may increase your dose to 300 mg once a day if your depression does not improve after several weeks.
Take your dose of WELLBUTRIN XL early in the morning.

Do not take WELLBUTRIN XL more than once each day.

Your doctor may alter your dose:

- if you have liver or kidney problems
- if you are over 65 years of age.

Swallow the tablets whole. Do not chew them, crush them or split them – 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).

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

How long to take it for:

Only you and your doctor can decide how long you should take WELLBUTRIN XL. 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 XL to prevent depression coming back. Do not stop taking WELLBUTRIN XL or reduce your dose without talking to your doctor first. Sometimes WELLBUTRIN XL tablets have an unusual smell**.** This is normal, carry on taking the tablets as usual.

If you take more WELLBUTRIN XL than you should:

If you take too many tablets, you may increase the risk of a seizure (fit)**.**

Other serious effects may also happen. **Don't delay**. Ask your doctor what to do or contact your nearest hospital emergency department at once.

If you forget to take WELLBUTRIN XL:

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.

4. Possible side effects:

WELLBUTRIN XL can have side effects.

Not all side effects reported for WELLBUTRIN XL are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking WELLBUTRIN XL, please consult your doctor, pharmacist or other healthcare provider for advice.

Seizures (fits):

Approximately 1 in every 1 000 people taking the maximum dose of WELLBUTRIN XL is at risk of a seizure (fit). The chance of this happening is higher if you take too much, if you take certain medicines in combination with WELLBUTRIN XL, or if you are at higher than usual risk of seizures (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 XL. 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.

Lupus skin rash or worsening of lupus symptoms:

Lupus is an immune system disorder affecting the skin and other organs. Very rarely (up to 1 in 10000) people may experience lupus skin rash or worsening of lupus symptoms while taking WELLBUTRIN XL.

Symptoms include:

- lupus flares
- skin rash or lesions (particularly on sun-exposed areas)

➔ **If you experience lupus skin rash or worsening of lupus symptoms contact your doctor straight away, as it might be necessary to stop the treatment.**

Disturbed sleep:

The most common side effect in people taking WELLBUTRIN XL is difficulty sleeping. Make sure you take your tablet early in the morning.

Other common side effects:

- headache, fever, dizziness, itching, sweating, skin rash, hives
- shakiness, tremor, chest pain
- feeling anxious or, agitated
- dry mouth, tummy pain or other upsets (feeling sick, vomiting, constipation), changes in the taste of food, loss of appetite
- changes in blood pressure, flushing
- ringing in the ears, visual disturbances.

Uncommon side effects:

- weakness, tiredness
- feeling depressed
- feeling confused
- difficulty concentrating
- raised heart rate
- weight loss.

The following side effects may occur:

- seizures (fits)
- palpitations, fainting
- rash with pus filled pimples/blisters (acute generalised exanthematous pustulosis)

- lupus skin rash or worsening of lupus symptoms (see the beginning of this section)
- uncontrolled movements, twitching, muscle stiffness, problems with walking or coordination
- stuttering
- feeling restless, irritable, hostile, aggressive or paranoid, feeling unreal or strange (depersonalisation), sensing or believing things that are not there (hallucinations/delusions), feeling of panic (panic attack), strange dreams, tingling or numbness, loss of memory.
- raised liver enzymes, yellowing of skin or the whites of your eyes (jaundice), hepatitis
- severe allergic reactions; rash together with joint and muscle pains, worsening of psoriasis
- changes in blood sugar levels
- urinating more or less than usual, uncontrollable urination
- decrease in blood sodium (hyponatraemia).

Talk about any troublesome side effects with your doctor or pharmacist. If you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

Thoughts of suicide or worsening of your condition:

If you are depressed, you can sometimes have thoughts of harming or killing yourself. These thoughts may be increased when first starting antidepressants.

These medicines can take time to work, usually about two weeks, but sometimes longer (see “Warnings and precautions”).

Children under 18 years of age:

WELLBUTRIN XL should not be used 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.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’S publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of WELLBUTRIN XL.

5. How to store WELLBUTRIN XL:

Keep out of the reach and sight of children.

Store at or below 25 °C. Keep well closed.

Store it in the original pack, in order to protect from humidity and light.

Do not use after the expiry date stamped on the outer pack.

If you have any WELLBUTRIN XL left over once you’ve finished treatment, take them back to the pharmacist.

6. Contents of the pack and other information:

What WELLBUTRIN XL contains:

The active ingredient is bupropion hydrochloride.

Each WELLBUTRIN XL 150 tablet contains 150 mg of bupropion hydrochloride.

Each WELLBUTRIN XL 300 tablet contains 300 mg of bupropion hydrochloride.

The other ingredients are:

Tablet core: Polyvinyl alcohol, glyceryl behenate

Film coat: Ethylcellulose 100, povidone, polyethylene glycol 1450, methacrylic acid copolymer dispersion (Eudragit L30 D-55), silicon dioxide, triethyl citrate, edible black ink (for printing) (containing Shellac glaze, isopropyl alcohol, Iron Oxide black, n-butyl alcohol, propylene glycol and ammonium hydroxide).

What WELLBUTRIN XL looks like and the contents of the pack:

WELLBUTRIN XL 150: Creamy white to pale yellow, round tablet, imprinted with 'GS 5FV 150' in black ink on one side and the other side plain.

WELLBUTRIN XL 300: Creamy white to pale yellow, round tablet, imprinted with 'GS 5YZ 300' in black ink on one side and the other side plain.

White opaque plastic HDPE bottles with white polypropylene plastic child-resistance closures, containing 30 tablets.

Holder of certificate of registration:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

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