**SCHEDULING STATUS:**

S5

## 1. NAME OF THE MEDICINE

**WELLBUTRIN XL 150 extended-release tablets**

**WELLBUTRIN XL 300 extended-release tablets**

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

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

Sugar-free.

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Extended-release tablets.

WELLBUTRIN XL 150: Creamy white to pale yellow, round tablet, imprinted with ‘GS5FV’ in black ink on one side and the other side plain.

WELLBUTRIN XL 300: Creamy white to pale yellow, round tablet, imprinted with ‘GS5YZ’ in black ink on one side and the other side plain.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

WELLBUTRIN XL is indicated for the treatment of depression as defined by DSM IV Criteria.

Following a satisfactory response, continuation with WELLBUTRIN XL therapy is effective in preventing relapse and preventing recurrence of further depressive episodes.

### 4.2 Posology and method of administration

Therapy should be initiated by medical practitioners experienced in the treatment of depression.

**Posology:**

**Initial treatment:**

The initial dose of WELLBUTRIN XL is 150 mg taken as a single daily dose in the morning. Patients who are not responding adequately to a dose of 150 mg/day may benefit from an increase to the usual adult target dose of 300 mg/day, given once daily. There should be an interval of at least 24 hours between successive doses.
Insomnia is a very common adverse event which is often transient. Insomnia may be reduced by avoiding dosing at bedtime (provided there is at least 24 hours between doses) or, if clinically indicated, dose reduction.

**Switching patients from sustained release tablets:**

When switching patients from sustained release tablets to extended-release tablets; give the same total daily dose when possible. Patients who are currently being treated with sustained release tablets at 300 mg/day (e.g., 150 mg twice daily) may be switched to extended-release tablets 300 mg once daily.

**Special populations:**

***Children and adolescents:*** WELLBUTRIN XL is not indicated for use in children or adolescents aged less than 18 years (see section 4.3).

***Elderly:*** Greater sensitivity of some elderly individuals to WELLBUTRIN XL cannot be ruled out, hence a reduced frequency and/or dose may be required (see section 4.4).

***Renal impairment:*** Treatment of patients with renal impairment should be initiated at a reduced frequency and/or dose, as bupropion and its metabolites may accumulate in such patients to a greater extent than usual (see section 4.4).

***Liver impairment:*** WELLBUTRIN XL should be used with caution in patients with mild liver impairment. Because of increased variability in WELLBUTRIN XL's pharmacokinetics in patients with mild hepatic cirrhosis, a reduced frequency of dosing should be considered (see sections 4.8 and 4.4). WELLBUTRIN XL is contraindicated in patients with moderate to severe hepatic cirrhosis.

**Method of administration:**

WELLBUTRIN XL tablets should be swallowed whole. The tablets should not be cut, crushed or chewed as this may lead to an increased risk of adverse effects including seizures.

### 4.3 Contraindications

- Hypersensitivity to bupropion hydrochloride or to any of the components of WELLBUTRIN XL listed in section 6.1.
- Patients under 18 years.
- WELLBUTRIN XL is contraindicated in patients with a seizure disorder.
- WELLBUTRIN XL should not be administered to patients currently being treated with any other preparation containing bupropion, as the incidence of seizures is dose dependent.
- WELLBUTRIN XL is contraindicated in patients with a known central nervous system tumour.
- WELLBUTRIN XL is contraindicated in patients undergoing abrupt discontinuation of alcohol or sedatives.

- WELLBUTRIN XL is contraindicated in patients with a current or previous diagnosis of bulimia or anorexia nervosa as a higher incidence of seizures was seen in this patient population when bupropion was administered.
- Concomitant administration of WELLBUTRIN XL with monoamine oxidase inhibitors (MAOIs) is contraindicated. At least 14 days should elapse between the discontinuation of MAOIs and initiation of treatment with WELLBUTRIN XL.
- WELLBUTRIN XL is contraindicated for use in patients with liver disease, Child-Pugh grades B and C, range 7-13
- Women of child-bearing potential not using contraception

### 4.4 Special warnings and precautions for use

**The recommended dose of WELLBUTRIN XL should not be exceeded, since bupropion is associated with a dose-related risk of seizure.**

WELLBUTRIN XL should be discontinued promptly if patients experience hypersensitivity reactions during treatment (see SIDE EFFECTS). Clinicians should be aware that symptoms may persist beyond the discontinuation of WELLBUTRIN XL and clinical management should be provided accordingly.

The overall incidence of seizure with WELLBUTRIN XL in clinical trials was approximately 0,1 %.

There is an increased risk of seizures occurring with the use of WELLBUTRIN XL in the presence of predisposing risk factors, which lower the seizure threshold. Therefore, WELLBUTRIN XL should not be administered to patients with one or more conditions predisposing to a lowered seizure threshold, which include:

- history of head trauma
- central nervous system (CNS) tumour
- history of seizures

- concomitant administration of other medications known to lower the seizure threshold excessive use of alcohol or sedatives (see section 4.3), diabetes treated with hypoglycaemics or insulin and use of stimulants or anorectic products.

WELLBUTRIN XL should be discontinued and is not recommenced in patients who experience a seizure while on treatment.

**Clinical worsening and suicide risk in adults associated with psychiatric disorders:**

Patients with major depressive disorder may experience worsening of their depression and/or the emergence of suicidal ideation and behaviours (suicidality) whether or not they are taking antidepressant medications. This risk may persist until significant remission occurs. A causal role, however, for antidepressant medicines in inducing such behaviour has not been established. As improvement may not occur during the first few weeks or more of treatment, patients being treated with WELLBUTRIN XL should be closely monitored for clinical worsening (including development of new symptoms) and suicidality, especially at the beginning of a course of therapy, or at the time of dose changes, either increases or decreases.

Patients with a history of suicidal behaviour or thoughts, young adults and those patients exhibiting a significant degree of suicidal ideation prior to commencement of treatment, are at a greater risk of suicidal thoughts or suicide attempts and should receive careful monitoring during treatment.

The following symptoms have been reported in patients being treated with antidepressants for major depressive disorder: anxiety, agitation, panic attacks, insomnia, irritability, hostility (aggressiveness), impulsivity, akathisia, hypomania and mania.

In addition, a meta-analysis of placebo controlled clinical trials of antidepressant medicines in adults with major depressive disorder and other psychiatric disorders showed an increased risk of suicidal thinking and behaviour associated with antidepressant use compared to placebo in patients less than 25 years old.

Patients (and caregivers of patients) should be alerted about the need to monitor for any worsening of their condition (including development of new symptoms) and/or the emergence of suicidal ideation/behaviour or thoughts of harming themselves and to seek medical advice immediately if these symptoms present. It should be recognised that the onset of neuropsychiatric symptoms could be related either to the underlying disease state or the medicine therapy and an appropriate patient assessment should be undertaken (see Neuropsychiatric symptoms including mania and bipolar disorder; section 4.8).

Consideration should be given to changing the therapeutic regimen, including discontinuing WELLBUTRIN XL, in patients who experience clinical worsening (including development of new symptoms) and/or the emergence of suicidal ideation/behaviour, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms. Although there is no need to taper WELLBUTRIN XL upon discontinuation, the patient should be monitored for worsening of depressive symptoms following discontinuation.

**Neuropsychiatric symptoms including mania and bipolar disorder:**

Neuropsychiatric symptoms have been reported (see section 4.8). In particular, psychotic and manic symptomatology has been observed, mainly in patients with a known history of psychiatric illness. Aggression, rage and violent behaviour may occur. Additionally, a major depressive episode may be the initial presentation of a bipolar disorder. It is generally believed (though not established in controlled trials) that treating such an episode with an antidepressant alone can increase the likelihood of precipitation of a mixed/manic episode in patients at risk for bipolar disorder. Limited clinical data on use of bupropion in combination with mood stabilisers in patients with a history of bipolar disorder suggests a low rate of switch to mania.

Prior to initiating treatment with WELLBUTRIN XL, patients should be adequately screened to determine if they are at risk for bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression.

**Hepatic impairment:**

Bupropion is extensively metabolised in the liver to active metabolites, which are further metabolised. No statistically significant differences in the pharmacokinetics of bupropion were observed in patients with mild hepatic cirrhosis compared with healthy volunteers, but bupropion plasma levels showed a higher variability between individual patients.
Therefore, WELLBUTRIN XL should be used with caution in patients with mild hepatic impairment and reduced frequency of dosing should be considered (see sections 5.2 and 4.3).

**Renal impairment and elderly patients:**

Bupropion is extensively metabolised in the liver to active metabolites which are further metabolised and excreted by the kidneys. Therefore treatment of patients with renal impairment should be initiated at reduced frequency and/or dose as bupropion and its metabolites may accumulate in such patients to a greater extent than usual. The patient should be closely monitored for possible adverse effects (e.g. insomnia, dry mouth, seizures) that could indicate high bupropion or metabolite levels, toxic effects of elevated blood and tissue levels of bupropion and metabolites.
Clinical experience with WELLBUTRIN XL has not identified any differences in tolerability between elderly and other adult patients. However, greater sensitivity of some elderly individuals cannot be ruled out, hence a reduced frequency and/or dose may be required (see section 5.2).

**Cardiovascular disease:**

There is insuffucient clinical experience of the use of WELLBUTRIN XL to treat depression in patients with cardiovascular disease.

Care should be exercised if WELLBUTRIN XL is used in these patients.

Hypertension has been reported to be severe and may require acute treatment, in patients receiving WELLBUTRIN XL. This has been observed in patients with and without pre-existing hypertension.

**Children and adolescents < 18 years:**

The safety and efficacy with the treatment of WELLBUTRIN XL tablets in patients under 18 years of age have not been established. Treatment with antidepressants is associated with an increased risk of suicidal thinking and behaviour in children and adolescents with major depressive disorder and other psychiatric disorders (see section 4.3).

**Inappropriate routes of administration:**

WELLBUTRIN XL is intended for oral use only. The inhalation of crushed tablets or injection of dissolved bupropion has been reported, and may lead to a rapid release, faster absorption and a potential overdose. Seizures and/or cases of death have been reported when WELLBUTRIN XL has been administered intra-nasally or by parenteral injection.

**Serotonin syndrome:**

Serotonin syndrome has been reported in association with overdose (see section 4.9).

## 4.5 Interaction with other medicines and other forms of interaction

Bupropion is metabolised to its major active metabolite hydroxybupropion primarily by the cytochrome P450 IIB6 (CYP2B6) (see Pharmacokinetic properties).

Care should therefore be exercised when WELLBUTRIN XL is co-administered with medicines known to affect the CYP2B6 isoenzyme (e.g., orphenadrine, cyclophosphamide, ifosfamide, ticlopidine, clopidogrel).

Although bupropion is not metabolised by the CYP2D6 isoenzyme, *in vitro* human P450 studies have shown that bupropion and hydroxybupropion are inhibitors of the CYP2D6 pathway. In a human pharmacokinetic study, administration of bupropion increased plasma levels of desipramine. This effect was present for at least 7 days after the last dose of bupropion. Concomitant therapy with medicines predominantly metabolised by this isoenzyme (such as certain beta-blockers, anti-dysrrhythmics, selective serotonin re-uptake inhibitors (SSRIs), tricyclic antidepressants (TCAs), antipsychotics) should be initiated at the lower end of the dose range of the concomitant medication. If WELLBUTRIN XL is added to the treatment regimen of a patient already receiving a medication metabolised by CYP2D6, the need to decrease the dose of the original medication should be considered, particularly for those concomitant medications with a narrow therapeutic index (see section 5.2).

Medicines which require metabolic activation by CYP2D6 in order to be effective (e.g. tamoxifen), may have reduced efficacy when administered concomitantly with inhibitors of CYP2D6 such as bupropion.

Although citalopram is not primarily metabolised by CYP2D6, in one study, bupropion increased the $C_{max}$ and AUC of citalopram by 30 % and 40 %, respectively.

Since bupropion is extensively metabolised, the co-administration of medicines known to induce metabolism (e.g., carbamazepine, phenobarbitone, phenytoin, ritonavir, efavirenz) or inhibit metabolism may affect its clinical activity.

In a series of studies in healthy volunteers, ritonavir (100 mg twice daily or 600 mg twice daily) or ritonavir 100 mg plus lopinavir 400 mg twice daily reduced the exposure of bupropion and its major metabolites in a dose dependent manner by approximately 20 % up to 80 %. Similarly, efavirenz 600 mg once daily for two weeks reduced the exposure of buproprion by approximately 55 %. This effect of ritonavir and efavirenz is thought to be due to the induction of

bupropion metabolism. Patients receiving efavirenz with WELLBUTRIN XL may need increased doses of WELLBUTRIN XL but the maximum recommended dose of WELLBUTRIN XL should not be exceeded.

There have been reports of adverse neuropsychiatric events or reduced alcohol tolerance in patients drinking alcohol during WELLBUTRIN XL treatment. The consumption of alcohol during WELLBUTRIN XL treatment should be avoided.

Clinical data suggest a higher incidence of adverse events in patients receiving concurrent administration of bupropion and levodopa. Administration of WELLBUTRIN XL to patients receiving either levodopa or amantadine concurrently should be undertaken with caution.

Concomitant use of WELLBUTRIN XL and a nicotine transdermal system (NTS) may result in elevations of blood pressure.

Coadministration of digoxin with WELLBUTRIN XL may decrease digoxin levels. Clinicians should be aware that digoxin levels may rise on discontinuation of WELLBUTRIN XL and the patient should be monitored for possible digoxin toxicity.

**Interactions involving laboratory tests:**

WELLBUTRIN XL has been reported to interfere with the assay used in some rapid urine drug screens, which can result in false positive readings, particularly for amphetamines. A more specific alternative chemical method should be considered to confirm a positive result.

## 4.6 Fertility, pregnancy and lactation

**Pregnancy:**

Safety in pregnancy and lactation has not been established.

WELLBUTRIN XL should not be used during pregnancy unless the clinical condition of the woman requires treatment with bupropion and alternative treatments are not an option.

Women of childbearing potential must use reliable contraception. Studies of pregnancy outcomes following maternal exposure to bupropion in pregnancy have reported an increased

risk of congenital cardiovascular malformations including ventricular septal defects and left outflow tract defects.

**Lactation:**

Safety in lactation has nbot been established. As bupropion and its metabolites are excreted in human breast milk, mothers should be advised not to breastfeed while taking WELLBUTRIN XL.

**Fertility:**

There are no data on the effect of bupropion on human fertility. A reproductive study in rats revealed no evidence of impaired fertility.

### 4.7 Effects on ability to drive and use machines

Patients should exercise caution before driving or use of machinery until they are reasonably certain WELLBUTRIN XL tablets do not adversely affect their performance.

### 4.8 Undesirable effects

The list below provides information on the undesirable effects identified from clinical experience, categorised by system organ class and frequency.

Frequencies are defined as: very common (≥ 1/10), common (≥ 1/100, < 1/10), uncommon (≥ 1/1 000, < 1/100), rare (≥ 1/10 000, < 1/1 000), very rare (≥ 1/10 000).

***Immune system disorders:****

Common: hypersensitivity reactions such as urticaria

Very rare: more severe hypersensitivity reactions including angioedema, dyspnoea/bronchospasm and anaphylactic shock. Arthralgia, myalgia and fever have also been reported in association with rash and other symptoms suggestive of delayed hypersensitivity. These symptoms may resemble serum sickness

** See also 'Skin and subcutaneous tissue disorders'*

***Metabolism and nutritional disorders:***

Common: anorexia

Uncommon: weight loss

Very rare: blood glucose disturbances

Not known: hyponatraemia

***Psychiatric disorders:***

Very common: insomnia

Common: agitation, anxiety

Uncommon: confusion, depression

Very rare: aggression, hostility, irritability, restlessness, hallucinations, abnormal dreams, depersonalisation, delusions, paranoid ideation

Not known: suicidal ideation, suicidal behaviour, psychosis

***Nervous system disorders:***

Very common: headache

Common: tremor, dizziness, taste disorders

Uncommon: concentration disturbance

Rare: seizures (see section 4.4)

Very rare: dystonia, ataxia, parkinsonism, incoordination, memory impairment, paraesthesia, syncope

***Eye disorders:***

Common: visual disturbance

***Ear and labyrinth disorders:***

Common: tinnitus

***Cardiac disorders:***

Uncommon: tachycardia

Very rare: palpitations

***Vascular disorders:***

Common: increased blood pressure (sometimes severe), flushing

Very rare: vasodilation, postural hypotension

***Gastrointestinal disorders:***

Very common: dry mouth, gastrointestinal disturbance including nausea and vomiting

Common: abdominal pain, constipation

***Hepatobiliary disorders:***

Rare: elevated liver enzymes, jaundice, hepatitis

***Skin and subcutaneous tissue disorders:****

Common: rash, pruritus, sweating

Very rare: erythema multiforme and Stevens-Johnson syndrome, exacerbation of psoriasis

** See also 'Immune system disorders'*

***Musculoskeletal and connective tissue disorders:***

Very rare: twitching

***Renal and urinary disorders:***

Very rare: urinary frequency and/or retention, urinary incontinence

***General disorders and administration site conditions:***

Common: fever, asthenia, chest pain.

**Reporting of suspected adverse reactions:**

Reporting suspected adverse reactions after authorisation of WELLBUTRIN XL is important. It allows continued monitoring of the benefit/risk balance of WELLBUTRIN XL. Health care providers are asked to report any suspected adverse reactions 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.

## 4.9 Overdose

In addition to those events reported under Side effects, overdose has resulted in symptoms including drowsiness, loss of consciousness and ECG changes such as conduction disturbances (including QRS prolongation) or dysrrhythmias – cases of fatal outcome have been reported. Serotonin syndrome has also been reported.

Acute ingestion of doses in excess of 10 times the maximum therapeutic dose has been reported.

**Treatment**:

In the event of overdose, hospitalisation is advised.

ECG and vital signs should be monitored.

Ensure an adequate airway, oxygenation and ventilation. The use of activated charcoal is recommended. No specific antidote for bupropion is known.

Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Category and class: A 1.2 Psycho-analeptics (antidepressants)

Bupropion is an inhibitor of the neuronal re-uptake of catecholamines (noradrenaline (norepinephrine) and dopamine) with minimal effect on the re-uptake of indolamines (serotonin), and does not inhibit monoamine oxidase.

The mechanism of action of bupropion is unknown.

### 5.2 Pharmacokinetic properties

***Absorption:*** Following oral administration of bupropion tablets to healthy volunteers, time to peak plasma concentrations for bupropion was approximately 5 hours.

The absorption of bupropion is not significantly affected when taken with food.

Bupropion and its metabolites exhibit linear kinetics following chronic administration of 150 to 300 mg per day.

***Distribution:*** Bupropion is widely distributed with an apparent volume of distribution of approximately 2000 ℓ. Bupropion and hydroxybupropion are moderately bound to plasma proteins (84 % and 77 %, respectively). The extent of protein binding of the threohydrobupropion metabolite is about half that seen with bupropion.

***Metabolism:*** Bupropion is extensively metabolised in humans. Three pharmacologically active metabolites have been identified in plasma: hydroxybupropion and the amino-alcohol isomers, threohydrobupropion and erythrohydrobupropion. These have clinical importance, as their plasma concentrations are as high as or higher than those of bupropion.
Peak plasma concentrations of hydroxybupropion occur approximately 7 hours following administration of WELLBUTRIN XL.
Erythrohydrobupropion cannot be measured in the plasma after a single dose of bupropion. The active metabolites are further metabolised to inactive metabolites and excreted in the urine.
*In vitro* studies indicate that bupropion is metabolised to its major active metabolite hydroxybupropion primarily by CYP2B6, while cytochrome P450s are not involved in the formation of threohydrobupropion (see section 4.5).
Bupropion and hydroxybupropion are both relatively weak competitive inhibitors of the CYP2D6 isoenzyme with Ki values of 21 and 13,3 µM, respectively. In human volunteers known to be extensive metabolisers of the CYP2D6 isoenzyme, co-administration of bupropion and desipramine has resulted in 2- and 5-fold increases in the Cmax and AUC, respectively, of desipramine. This effect was present for at least 7 days after the last dose of bupropion. Since bupropion is not metabolised by the CYP2D6 pathway, desipramine is not anticipated to affect the pharmacokinetics of bupropion. Caution is advised when bupropion is administered with substrates for the CYP2D6 pathway (see section 4.5).

In humans, there is no evidence of enzyme induction of bupropion or hydroxybupropion in volunteers or patients receiving recommended doses of bupropion for 10 to 45 days.

***Elimination:*** Following oral administration of 200 mg of 14C-bupropion in humans, 87 % and 10 % of the radioactive dose were recovered in the urine and faeces, respectively. The fraction of the dose of bupropion excreted unchanged was only 0,5 %, a finding consistent with the extensive metabolism of bupropion. Less than 10 % of this 14C dose was accounted for in the urine as active metabolites.

The mean apparent clearance following oral administration of bupropion is approximately 200 ℓ/hr and the mean elimination half-life of bupropion is approximately 20 hours.

The elimination half-life of hydroxybupropion is approximately 20 hours and its area under the plasma drug concentration versus time curve (AUC) at steady state is approximately 17 times that of bupropion. The elimination half-lives for threohydrobupropion and erythrohydrobupropion are longer (37 and 33 hours, respectively) and steady-state AUC values are 8 and 1,6 times higher than that of bupropion, respectively. Steady state for bupropion and its metabolites is reached within 8 days.

The insoluble shell of the extended-release tablets may remain intact during gastrointestinal transit and be eliminated in the faeces.

**Special patient populations:**

***Elderly:*** Pharmacokinetic studies in the elderly have shown variable results. A single dose study showed that the pharmacokinetics of bupropion and its metabolites in the elderly do not differ from those in the younger adults. Another pharmacokinetic study, single and multiple doses, has suggested that accumulation of bupropion and its metabolites may occur to a greater extent in the elderly. Clinical experience has not identified differences in tolerability between elderly and younger patients, but greater sensitivity in older patients cannot be ruled out.

***Patients with renal impairment:*** The elimination of bupropion and its major metabolites may be reduced by impaired renal function (see section 4.4).

***Patients with hepatic impairment:*** The pharmacokinetics of bupropion and its active metabolites were not statistically significantly different in patients with mild cirrhosis (Child-Pugh grade A, range 5-6) when compared to healthy volunteers, although more variability was observed between individual patients. For patients with moderate to severe hepatic cirrhosis (Child Pugh grades B & C, range 7-13), a single dose of bupropion produced a Cmax and AUC that were substantially increased (mean difference approximately 70 % and 3-fold, respectively) and more variable when compared to the values in healthy volunteers; the mean half-life was also longer (by approximately 40 %). For the metabolites, the mean Cmax was lower (by approximately 30 to 70 %), the mean AUC tended to be higher (by approximately 30 to 50 %), the median Tmax was later (by approximately 20 hrs), and the mean half-lives were longer (by approximately 2 to 4-fold) than in healthy volunteers (see section 4.3).

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

***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 (E172), n-butyl alcohol, propylene glycol and ammonium hydroxide).

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

18 months.

### 6.4 Special precautions for storage

Store at or below 25 °C.

Store in the original container in order to protect from humidity and light.

Keep well closed.

### 6.5 Nature and contents of container

WELLBUTRIN XL 150: White opaque plastic HDPE bottles with white polypropylene plastic child-resistance closures, containing 30 tablets.

WELLBUTRIN XL 300: White opaque plastic HDPE bottles with white polypropylene plastic child-resistance closures, containing 30 tablets.

### 6.6 Special precautions for disposal and other handling

No special requirements for disposal.

## 7. HOLDER OF CERTIFICATE OF REGISTRATION

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

## 8. REGISTRATION NUMBERS

WELLBUTRIN XL 150: 41/1.2/0371

WELLBUTRIN XL 300: 41/1.2/0372

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15 August 2008

## 10. DATE OF REVISION OF THE TEXT

07 July 2022

GDS 23-27&29

**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 health care 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 health care 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

- 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.

Talk to your doctor 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.

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 health care 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.

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

- if you take medicines which make seizures (fits) more likely e.g. theophyhylline 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
- 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:**

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 health care 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 health care 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.

**D*isturbed 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
- uncontrolled movements, twitching, muscle stiffness, problems with walking or coordination
- feeling restless, irritable, hostile, aggressive or paranoid, feeling unreal or strange (depersonalisation), sensing or believing things that are not there (hallucinations/delusions), 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: htpp://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 'GS5FV' in black ink on one side and the other side plain**.**

WELLBUTRIN XL 300: Creamy white to pale yellow, round tablet, imprinted with 'GS5YZ' 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

**This leaflet was last revised:**

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**Registration numbers:**

WELLBUTRIN XL 150: 41/1.2/0371

WELLBUTRIN XL 300: 41/1.2/0372

**Date of registration:**

15 August 2008

GDS 23-27&29

**SKEDULERINGSTATUS:** S5

**WELLBUTRIN XL 150-verlengdevrystellingtablette**

**WELLBUTRIN XL 300-verlengdevrystellingtablette**

**Bupropioonhidrochloried**

Suikervry.

**Lees hierdie hele voubiljet aandagtig deur alvorens u begin om WELLBUTRIN XL te neem.**

- Hou hierdie voubiljet. U sal dit dalk weer moet lees.
- As u verdere vrae het, moet u asseblief u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer vra.
- WELLBUTRIN XL is aan u persoonlik voorgeskryf en u moenie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al is hul simptome dieselfde as u s'n.
- As u enige newe-effekte ervaar, praat met u dokter of apteker, verpleegkundige of ander gesondheidsorgverskaffer. Dit sluit enige moontlik newe-effekte in wat nie in hierdie voubiljet ingesluit is nie. Verwys na afdeling 4.

**Wat in hierdie voubiljet vervat word:**

6. Inhoud van die pakkie en ander inligting

## 1. WAT WELLBUTRIN XL IS EN WAARVOOR DIT GEBRUIK WORD

- WELLBUTRIN XL is medisyne wat deur u dokter voorgeskryf is om u depressie mee te behandel. Daar word gemeen dat dit inwerk op chemikalieë in die brein wat noradrenalien en dopamien genoem word. Dié chemikalieë hou met depressie verband.
- **Dit kan moontlik ’n rukkie duur voordat u begin beter voel**. Dit vat ’n rukkie vir WELLBUTRIN XL om ’n volle effek te hê – soms weke of maande. U dokter kan u moontlik aanraai om aan te hou om WELLBUTRIN XL te neem wanneer u begin beter voel om te voorkom dat die depressie terugkeer.
- **U dokter het hierdie medisyne gekies omdat dit vir u en u toestand gepas is.** Moet dit nie vir ander mense gee nie. Voordat daar op behandeling met WELLBUTRIN XL besluit is, sou u en u dokter waarskynlik die risiko’s vir leed en die voordele wat dit waarskynlik vir u sal inhou, bespreek het. Hierdie voubiljet sal u help om WELLBUTRIN XL veilig te neem.

## 2. WAT U MOET WEET ALVORENS U WELLBUTRIN XL NEEM:

**Moenie in die volgende gevalle WELLBUTRIN XL neem nie:**

- as u weet dat u vir WELLBUTRIN XL, bupropioon, of enige van die ander bestanddele in WELLBUTRIN XL-tablette allergies is (dit word in afdeling 6 uiteengesit).
- as u enige ander medisyne neem wat bupropioon bevat.
- as u met epilepsie gediagnoseer is, of ’n geskiedenis van toevalle (stuipe) het.
- as u ’n breingewas het.
- as u ’n eetversteuring het, of tevore gehad het (bv. bulimie of anorexia nervosa).
- as u gewoonlik ’n swaar drinker is wat onlangs opgehou drink het, of binnekort gaan ophou drink.
- as u onlangs opgehou het om susmiddels of kalmeermiddels te neem, of as u gaan ophou om dit te neem terwyl u WELLBUTRIN XL neem.

- as u in die afgelope 14 dae ander medisyne vir depressie geneem het wat monoamienoksidase-inhibitors (MAOI's) genoem word.
- as u erge lewerprobleme het.
- as u jonger as 18 jaar oud is. Daar is 'n verhoogde risiko vir selfdoodgedagtes en -gedrag wanneer kinders jonger as 18 jaar oud met antidepressante behandel word.
- As enige hiervan op u van toepassing is, praat dadelik met u dokter en moenie WELLBUTRIN XL neem nie.
- as u 'n vrou is wat swanger kan raak en nie voorbehoeding gebruik nie.

**Waarskuwings en voorsorgmaatreëls:**

Praat in die volgende gevalle met u dokter alvorens u WELLBUTRIN XL neem:

- as u in die verlede enige stuipe of toevalle gehad het
- as u 'n breingewas het
- as u probleme met u lewer of niere het
- as u dikwels baie alkohol gebruik
- as u aan diabetes ly waarvoor u insulien of tablette gebruik
- as u enige geestesgesondheidstoestand afgesien van depressie gehad het
- as u 'n ernstige hoofbesering gehad het
- as u ouer as 65 jaar oud is
- as u swanger is of van plan is om binnekort swanger te raak
- as u aan hoë bloeddruk ly.

As enige van die bogenoemde op u van toepassing is, is dit moontlik dat u dokter spesiale aandag aan u sorg sal wil skenk, of ander behandeling sal aanbeveel.

***Selfdoodgedagtes of verergering van u toestand:***

Dit is moontlik om soms gedagtes van selfleed of selfdood te hê as mens depressief is.

Hierdie gedagtes kan moontlik erger wees wanneer mens aanvanklik begin om antidepressante

te neem. Al hierdie soort medisynes neem tyd om te werk; soms sowat twee weke, maar partykeer langer.

Die kans is groter dat u hierdie gedagtes sal hê:

- as u tevore daaraan gedink het om selfdood te pleeg of om uself leed aan te doen
- as u jonger as 25 jaar oud is
- as u voel dat u depressie erger word

As u te eniger tyd daaraan dink om uself leed aan te doen of selfdood te pleeg, kry so gou as moontlik mediese advies (by ’n dokter of hospitaal).

**Ander medisynes en WELLBUTRIN XL**

Sê altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik. (Dit sluit aanvullende of tradisionele medisynes in.)

Sê vir u dokter as u in die afgelope 14 dae ander medisyne vir depressie geneem het wat monoamienoksidase-inhibitors (MAOI’s) genoem word, en moenie WELLBUTRIN XL neem nie.

Sê vir u dokter as u enige ander medisynes, kruie of vitamiene (ook produkte wat u self aangekoop het) gebruik. Hy of sy sal moontlik u dosis WELLBUTRIN XL aanpas, of aanbeveel dat u u ander medikasies aanpas.

Sommige medisynes moenie saam met WELLBUTRIN XL geneem word nie. Sommige daarvan kan die kans op toevalle (stuipe) verhoog. Ander medisynes kan moontlik die risiko vir ander newe-effekte verhoog. Van die voorbeelde word hier onder genoem, maar die lys is nie allesomvattend nie.

***Daar kan moontlik ’n hoër kans as gewoonlik wees vir toevalle (stuipe):***

- as u medisynes neem wat toevalle (stuipe) waarskynliker maak, soos byvoorbeeld teofillien vir asma of longsiekte, of tramadol (’n sterk pynstiller)
- as u susmiddels of kalmeermiddels geneem het, of as u gaan ophou om dit te neem terwyl u WELLBUTRIN XL neem
  - as u stimulante of ander medisynes gebruik om u gewig of eetlus te beheer
  - as u medisynes teen malaria neem (soos meflokien of chlorokien)
  - as u antibiotika neem wat kinolone genoem word

As enige hiervan op u van toepassing is, praat dadelik met u dokter voordat u WELLBUTRIN XL neem.

***Daar kan moontlik ’n hoër kans as gewoonlik vir ander newe-effekte wees:***

- as u sekere ander medisynes vir depressie of ’n ander geestesgesondheidstoestand neem
- as u medisyne vir Parkinson se siekte neem (levodopa, amantadien of orfenadrien)
- as u medisyne neem wat vir epilepsie gebruik word (karbamasepien, fenitoïen of fenobarbitoon)
- as u siklofosfamied of ifosfamied gebruik (dit word hoofsaaklik vir die behandeling van kanker gebruik)
- as u tiklopidien of klopidogrel neem (dit word hoofsaaklik gebruik om beroerte te voorkom)
- as u sommige betablokkers neem
- as u medisynes vir u hartritme neem
- as u nikotienplakkers gebruik om u te help om op te hou rook

As enige hiervan op u van toepassing is, praat dadelik met u dokter voordat u WELLBUTRIN XL neem.

***WELLBUTRIN XL kan moontlik ander medisynes minder doeltreffend maak:***

Sê vir u dokter as u digoksien vir u hart neem. U dokter kan dit moontlik oorweeg om u dosis digoksien aan te pas.

***Laboratoriumtoetse:***

WELLBUTRIN XL kan moontlik inmeng met die resultate van sommige urientoetse wat gebruik word om ander medisynes of middels op te spoor. As u ’n urientoets nodig het, sê vir u dokter dat u WELLBUTRIN XL neem.

**WELLBUTRIN XL saam met kos, drinkgoed en alkohol:**

Sommige mense meen dat hulle sensitiewer vir alkohol is wanneer hulle WELLBUTRIN XL neem, en u dokter kan moontlik aanbeveel dat u nie alkohol (bier, wyn, sterk drank) gebruik terwyl u WELLBUTRIN XL neem nie, of dat u baie min alkohol gebruik. As u egter nou baie alkohol gebruik, moet u nie skielik ophou drink nie: dit kan moontlik riskant wees. Praat met die dokter oor die gebruik van alkohol voordat u begin om WELLBUTRIN XL te neem.

**Swangerskap en borsvoeding:**

As u swanger is of borsvoed, vermoed dat u swanger is of van plan is om swanger te raak, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u WELLBUTRIN XL neem.

U moenie WELLBUTRIN XL neem wanneer u swanger is nie.
Studies het getoon dat daar ’n toename was in die risiko vir geboortedefekte (spesifiek hartdefekte) by babas wie se ma’s WELLBUTRIN XL geneem het.
As u ’n vrou is wat swanger kan raak, moet u betroubare voorbehoeding gebruik.
Moeders wat WELLBUTRIN XL gebruik, moenie hulle babas borsvoed nie.

**Bestuur van ’n voertuig en gebruik van masjiene:**

As WELLBUTRIN XL u duiselig of lighoofdig laat voel, moenie ’n voertuig bestuur of enige gereedskap of masjiene gebruik nie.

## 3. Hoe om WELLBUTRIN XL te neem

Moenie medisynes wat vir u voorgeskryf is met enige ander persoon deel nie.
Neem altyd WELLBUTRIN XL presies soos wat u dokter gesê het u moet dit neem. Maak seker by u dokter of apteker as u nie seker is nie.

**Hoeveel om te neem:**

Die gewone aanvangsdosis vir volwassenes is een 150 mg-tablet elke dag.

U dokter kan moontlik u dosis na 300 mg een keer per dag verhoog as u depressie nie ná etlike weke verbeter nie.
Neem u dosis WELLBUTRIN XL vroeg in die oggend.
Moenie WELLBUTRIN XL meer as een keer per dag neem nie.
Die tablet is bedek met ’n omhulsel wat medisyne stadig in mens se liggaam vrystel. U kan moontlik iets in u stoelgang oplet wat soos ’n tablet lyk. Dit is die leë omhulsel wat uit u liggaam uitgeskei word.

**U dokter kan moontlik in die volgende gevalle u dosis verander:**

- as u probleme met u lewer of niere het
- as u ouer as 65 jaar oud is

**Sluk die tablette heel in**. Moenie die tablette kou, stukkend maak of in die helfte breek nie.
As u dit doen, sal die medisyne te vinnig in u liggaam vrygestel word. As dit gebeur, is die kans groter dat u newe-effekte kan ervaar, insluitend toevalle (stuipe).

**Neem altyd WELLBUTRIN XL presies soos u dokter dit voorgeskryf het.** Hierdie is die gewone dosisse, maar u dokter se advies is spesifiek op u van toepassing. Maak by u dokter of apteker seker as u onseker is.

**Hoe lank u die medisyne moet neem:**
Net u en u dokter kan besluit hoe lank u WELLBUTRIN XL moet neem. Dit kan moontlik weke of maande van behandeling neem vir u om enige verbetering te sien. Bespreek dikwels u simptome met u dokter om te besluit hoe lank u dit behoort te neem. U dokter kan u moontlik aanraai om aan te hou om WELLBUTRIN XL te neem wanneer u begin beter voel om te voorkom dat die depressie terugkeer. Moenie ophou om WELLBUTRIN XL te neem of u dosis verminder sonder om eers met u dokter te praat nie.
Soms kan WELLBUTRIN XL-tablette vreemd ruik**.** Dit is normaal: hou aan om die tablette soos gewoonlik te neem.

**As u meer WELLBUTRIN XL neem as wat u behoort te neem:**

As u te veel tablette neem, kan u moontlik die risiko vir ’n toeval (stuipe) verhoog**.**

Ander ernstige effekte kan moontlik ook voorkom. **Moenie wag nie**. Vra u dokter wat u te doen staan, of kontak dadelik u naaste hospitaal se noodgevalle-afdeling.

**As u vergeet om WELLBUTRIN XL** te neem:

As u ’n dosis oorslaan, wag en neem u volgende tablet op die gewone tyd. **Moenie ’n tablet neem om die vergete dosis** in te haal nie.

## 4. Moontlike newe-effekte

WELLBUTRIN XL kan newe-effekte veroorsaak.

Nie alle newe-effekte wat vir WELLBUTRIN XL aangemeld is, word by hierdie voubiljet ingesluit nie. Sou u algemene gesondheid versleg, of as u enige ongunstige effekte ervaar terwyl u WELLBUTRIN XL neem, kontak asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies.

**Toevalle (stuipe):**

Ongeveer 1 uit elke 1 000 mense wat die maksimum dosis van WELLBUTRIN XL neem, loop die risiko vir ’n toeval (stuipe). Die kans hiervoor is hoër as u te veel neem, as u sekere medisynes saam met WELLBUTRIN XL neem, of as u ’n hoër as gewone risiko vir toevalle (stuipe) het.

Praat met u dokter as u bekommerd is. As u stuipe kry, moet u vir u dokter sê sodra u herstel het. Moenie nog tablette neem nie.

**Allergiese reaksies:**

Sommige mense kan moontlik allergiese reaksies op WELLBUTRIN XL ervaar. Dit sluit die volgende in:

- rooi vel of veluitslag (soos netelroos), blase of knoppe op die vel wat jeuk (galbulte). Sommige veluitslagte kan moontlik hospitaalbehandeling noodsaak, veral as u mond of oë ook seer is
- ongewone fluithoes of asemnood
- geswelde ooglede, lippe of tong
- pyn in die spiere of gewrigte
- ineenstorting of verlies aan bewussyn

Kontak dadelik ’n dokter as u enige tekens van ’n allergiese reaksie het. Moenie nog tablette neem nie. Allergiese reaksies kan lank voortduur. Maak seker u voltooi die kursus as u dokter iets aan u voorskryf om met allergiesimptome te help.

**Ander newe-effekte:**

Algemene newe-effekte: dié kan moontlik meer as een uit tien mense affekteer

- Sukkel om te slaap. Maak seker dat u WELLBUTRIN XL vroeg in die oggend neem
- Hoofpyn
- Droë mond
- Voel mislik, braking
- Koors, duiseligheid, gejeuk, sweet en veluitslag (soms as gevolg van ’n allergiese reaksie)
- Bewerigheid, tremor, swakheid, moegheid, borskaspyn
- Voel angstig of ontsteld
- Maagpyn of ander ongesteldhede (hardlywigheid), verandering in hoe kos smaak, verlies aan eetlus (anoreksie)
- Toename in bloeddruk (soms erg), blosing
- Suising in die ore, visieversteurings

Nie-algemene newe-effekte (kan moontlik tot een uit elke 100 mense affekteer)

- Voel depressief (verwys ook na afdeling 2: “Neem in die volgende gevalle spesiale sorg met WELLBUTRIN XL” onder die opskrif: “Selfdoodgedagtes en verergering van u depressie”)
- Voel verward
- Konsentrasieprobleme
- Verhoogde harttempo
- Gewigsverlies
- Toevalle
- Vergeling van die vel of die wit van die oë (geelsug) wat moontlik deur verhoogde lewerensiemvlakke veroorsaak kan word, hepatitis
- Hartkloppings, floute
- Spiertrekkings, spierstyfheid, ongekontroleerde bewegings, probleme om te loop of met koördinasie
- Voel rusteloos, prikkelbaar, vyandig, aggressief, ervaar vreemde drome, tinteling of gevoelloosheid of geheueverlies
- Erge allergiese reaksies; veluitslag wat met gewrig- en spierpyn gepaard gaan
- Veranderinge in die bloedsuikervlak
- Urineer meer of minder as gewoonlik
- Urieninkontinensie (onwillekeurige urinering, urien wat lek)
- Afname in die vlak van natrium in die bloed (hiponatremie)
- Erge veluitslagte wat moontlik die mond en ander dele van die liggaam aantas en lewensgevaarlik kan wees
- Verergering van psoriase (verdikte kolle rooi vel)
- Voel onwerklik of vreemd (depersonalisering), sien of hoor dinge wat nie daar is nie (hallusinasies), voel dinge aan of glo dinge wat nie waar is nie (delusies), erge agterdogtigheid (vervolgingswaan)

Praat met u dokter of apteker oor enige hinderlike newe-effekte. As u enige newe-effekte opmerk wat nie in hierdie voubiljet genoem word nie, moet u asseblief u vir u dokter of apteker sê.

**Selfdoodgedagtes of verergering van u toestand:**

Dit is moontlik om soms gedagtes van selfleed of selfdood te hê as mens depressief is. Hierdie gedagtes kan moontlik erger wees wanneer mens aanvanklik begin om antidepressante te neem. Al hierdie soort medisynes neem tyd om te werk; soms sowat twee weke, maar partykeer langer (verwys ook na afdeling 2: “Neem in die volgende gevalle spesiale sorg met WELLBUTRIN XL”).

**Kinders wat jonger as 18 jaar oud is:**

WELLBUTRIN XL moenie gebruik word om kinders jonger as 18 jaar oud te behandel nie. Daar is ’n verhoogde risiko vir selfdoodgedagtes en -gedrag wanneer kinders jonger as 18 jaar oud met antidepressante behandel word.

**Aanmelding van newe-effekte:**

Praat met u dokter of apteker of verpleegkundige as u newe-effekte ervaar. U kan ook newe-effekte by Sahpra aanmeld deur die **“6.04 Adverse Drug Reaction Reporting Form”** te gebruik wat aanlyn onder Sahpra-publikasies beskikbaar is: htpp://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van WELLBUTRIN XL te verskaf.

## 5. Hoe om WELLBUTRIN XL te bewaar

Hou buite die bereik en sig van kinders.

Bewaar by of onder 25 °C. Hou goed toe.

Bewaar dit in die oorspronklike pakkie om dit teen vogtigheid en lig te beskerm.

Moenie gebruik ná die vervaldatum wat op die buitenste pakkie gedruk is nie.

As daar enige WELLBUTRIN XL oorbly nadat u u behandeling voltooi het, neem dit terug na die apteker. Moenie WELLBUTRIN XL in water of huishoudelike vullis weggooi nie.

## 6. Inhoud van die pakkie en ander inligting

**WELLBUTRIN XL bevat die volgende:**

Die aktiewe bestanddeel is bupropioonhidrochloried.

Elke WELLBUTRIN XL 150-tablet bevat 150 mg-bupropioonhidrochloried.

Elke WELLBUTRIN XL 300-tablet bevat 300 mg-bupropioonhidrochloried.

Die ander bestanddele is:

Kern van die tablet: Polivinielalkohol, gliserielbehenaat

Filmbedekking: Etielsellulose 100, povidoon, poliëtileenglikol 1450, metakrielsuurkopolimeerdispersie (Eudragit L30 D-55), silikoondioksied, triëtielsitraat, eetbare swart ink (vir drukdoeleindes) (dit bevat skellakglasuur, isopropielalkohol, swart ysteroksied, N-butielalkohol, propileenglikol en ammoniumhidroksied).

**Hoe WELLBUTRIN XL lyk, en wat die inhoud van die pakkie is:**

WELLBUTRIN XL 150: Roomwit tot liggeel ronde tablet waarop “GS5FV” in swart ink aan een kant gedruk is, en die ander kant leeg gelaat is**.**

WELLBUTRIN XL 300: Roomwit tot liggeel ronde tablet waarop “GS5YZ” in swart ink aan een kant gedruk is, en die ander kant leeg gelaat is.

Wit, ondeursigtige plastiek-HDPE-bottels met wit kinderbestande doppies van polipropileenplastiek wat 30 tablette bevat.

**Houer van die registrasiesertifikaat:**

GlaxoSmithKline South Africa (Pty.) Ltd.

Hawkinslaan 39

Epping Industria 1, 7460

**Hierdie voubiljet is laas hersien op:**

7 Julie 2022

**Registrasienommers:**

WELLBUTRIN XL 150: 41/1.2/0371

WELLBUTRIN XL 300: 41/1.2/0372

**Registrasiedatum:**

15 Augustus 2008

GDS 23-27&29