WELLBUTRIN XL

SCHEDULING STATUS:

S5

PROPRIETARY NAME AND DOSAGE FORM:

WELLBUTRIN XL 150 Extended-Release Tablets

WELLBUTRIN XL 300 Extended-Release Tablets

COMPOSITION:

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

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

Excipients:

Sugar-free.

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).

PHARMACOLOGICAL CLASSIFICATION:

A 1.2 Psycho-analeptics (antidepressants)

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

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.

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 2 000 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 INTERACTIONS).

Bupropion and hydroxybupropion are both relatively weak competitive inhibitors of the CYP2D6 isoenzyme with K_i 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 C_{max} 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 INTERACTIONS).

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 ^{14}C-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 ^{14}C 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.

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 WARNINGS AND SPECIAL PRECAUTIONS).

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

C_{max} 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 C_{max} was lower (by approximately 30 to 70 %), the mean AUC tended to be higher (by approximately 30 to 50 %), the median T_{max} was later (by approximately 20 hrs), and the mean half-lives were longer (by approximately 2 to 4-fold) than in healthy volunteers (see CONTRA-INDICATIONS).

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.

CONTRA-INDICATIONS:

- Patients under 18 years.
- Hypersensitivity to any component of the preparation.
- WELLBUTRIN XL is contra-indicated 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 contra-indicated in patients undergoing abrupt discontinuation of alcohol or sedatives.

- WELLBUTRIN XL is contra-indicated 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 contra-indicated. At least 14 days should elapse between the discontinuation of MAOIs and initiation of treatment with WELLBUTRIN XL.
- Liver disease, Child-Pugh grades B and C, range 7-13.

WARNINGS AND SPECIAL PRECAUTIONS:

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 CONTRA-INDICATIONS), diabetes treated with hypoglycaemics or insulin and use of stimulants or anorectic products.

WELLBUTRIN XL should be discontinued and 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 order: 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 below; SIDE EFFECTS). Consideration should be given to changing the therapeutic regimen, including possibly 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 SIDE EFFECTS). 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 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 Pharmacokinetic properties and CONTRA-INDICATIONS).

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 Pharmacokinetic properties).

Cardiovascular disease: There is limited clinical experience of the use of WELLBUTRIN XL to treat depression in patients with cardiovascular disease. A causal relationship between the use of WELLBUTRIN XL and sudden death cannot be excluded. Care should be exercised if WELLBUTRIN XL is used in these patients.

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 CONTRA-INDICATIONS).

Effects on Ability to Drive and Use Machinery: Patients should exercise caution before driving or use of machinery until they are reasonably certain WELLBUTRIN XL tablets do not adversely affect their performance.

INTERACTIONS:

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 Pharmacokinetic properties).

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) 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 to 80 %. This effect is thought to be due to the induction of bupropion metabolism. Patients receiving ritonavir 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 minimised or avoided.

Limited 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.

PREGNANCY AND LACTATION:

Pregnancy:

Safety in pregnancy and lactation has not been established.

Epidemiological studies of pregnancy outcomes following maternal exposure to bupropion in the first trimester have reported an association with increased risk of some congenital cardiovascular malformations, including ventricular septal defects and left ventricular outflow tract defects. These findings are not consistent across studies.

Lactation:

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

DOSAGE AND DIRECTIONS FOR USE:

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

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.

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.

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.

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 CONTRA-INDICATIONS).

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 WARNINGS AND SPECIAL PRECAUTIONS).

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 WARNINGS AND SPECIAL PRECAUTIONS).

Liver Impairment: WELLBUTRIN XL should be used with caution in patients with mild liver impairment. Because of increased variability in the pharmacokinetics in patients with mild hepatic cirrhosis, a reduced frequency of dosing should be considered (see SIDE EFFECTS and WARNINGS AND SPECIAL PRECAUTIONS). WELLBUTRIN XL is contra-indicated in patients with moderate to severe hepatic cirrhosis.

SIDE 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

Very common: weight loss

Very rare: blood glucose disturbances

Psychiatric disorders:

Very Common: insomnia

Common: agitation, anxiety

Uncommon: confusion, depression

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

Nervous system disorders:

Very Common: headache

Common: tremor, dizziness, taste disorders

Uncommon: concentration disturbance

Rare: seizures (see WARNINGS AND SPECIAL PRECAUTIONS)

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: errythema multiforme and Stevens-Johnson syndrome

** See also 'Immune system disorders'*

Musculoskeletal and connective tissue disorders:

Very rare: twitching

Renal and urinary disorders:

Very rare: urinary frequency and/or retention

General disorders and administration site conditions:

Common: fever, asthenia, chest pain.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS:

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.

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.

IDENTIFICATION:

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.

PRESENTATION:

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.

STORAGE INSTRUCTIONS:

Store at or below 25 °C.

Keep well closed.

Keep out of reach of children.

REGISTRATION NUMBERS:

WELLBUTRIN XL 150: 41/1.2/0371

WELLBUTRIN XL 300: 41/1.2/0372

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

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MANUFACTURER:

Valeant Pharmaceutical International, Inc

100 LifeSciences Parkway, Steinbach, Manitoba, R5G 1Z7, Canada

Namibia:

WELLBUTRIN XL 150 – Reg No. 10/1.2/0327 NS3

WELLBUTRIN XL 300 – Reg No. 10/1.2/0328 NS3

Patient Information Leaflet

SCHEDULING STATUS:

S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

WELLBUTRIN XL 150 Extended-Release Tablets

WELLBUTRIN XL 300 Extended-Release Tablets

Bupropion hydrochloride

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 or your pharmacist.
- 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.

WHAT WELLBUTRIN XL CONTAINS:

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).

Sugar-free.

WHAT WELLBUTRIN XL 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.

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
- if you are taking any other medicines which contain bupropion
- if you have been diagnosed with epilepsy

- 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 pregnant or breastfeeding
- if you are less 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.

Take special care with WELLBUTRIN XL:

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 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).

Taking WELLBUTRIN XL with food and drink:

Drinking 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 lactation:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking WELLBUTRIN XL.

If you are pregnant, or think you could be, or if you are planning to become pregnant do not take WELLBUTRIN XL without checking with your doctor. Studies have reported an increase in the risk of birth defects, particularly heart defects, in babies whose mothers were taking WELLBUTRIN XL.

Driving and using machinery:

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

Taking other medicines with WELLBUTRIN XL:

Always tell your healthcare profession 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. 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.

HOW TO TAKE WELLBUTRIN XL:

Always take WELLBUTRIN exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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.

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 this medicine, please consult your doctor, pharmacist or other healthcare professional 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.

Other side effects:

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
- 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
- changes in blood sugar levels
- urinating more or less than usual.

Talk about any troublesome side effects with your doctor or pharmacist. If you notice any side effects not listed 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 'Take special care with WELLBUTRIN XL').**

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.

STORING AND DISPOSING OF 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, out of direct sunlight.

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.

PRESENTATION OF WELLBUTRIN XL:

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.

IDENTIFICATION OF WELLBUTRIN XL:

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.

REGISTRATION NUMBER:

WELLBUTRIN XL 150: 41/1.2/0371

WELLBUTRIN XL 300: 41/1.2/0372

NAME AND ADDRESS OF REGISTRATION HOLDER:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

DATE OF PUBLICATION:

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GDS-17+22

Pasiëntinligtingsbrosjure

SKEDULERINGSTATUS:

S5

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM:

WELLBUTRIN XL 150 Verlengde-Vrystelling Tablette

WELLBUTRIN XL 300 Verlengde-Vrystelling Tablette

Bupropioonhidrochloried

Lees hierdie hele brosjure versigtig voordat jy begin om WELLBUTRIN XL te gebruik.

- Hou hierdie brosjure. Jy mag dit weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter of jou apteker.
- WELLBUTRIN XL is vir jou persoonlik voorgeskryf en jy moet dit nie vir ander mense gee nie. Dit kan hulle skade aandoen, al is hulle simptome dieselfde as joune.

WAT WELLBUTRIN XL BEVAT:

Elke WELLBUTRIN XL 150 tablet bevat 150 mg bupropioonhidrochloried.

Elke WELLBUTRIN XL 300 tablet bevat 300 mg bupropioonhidrochloried.

Die ander bestanddele is:

Tabletpit: Polivinielalkohol, gliserielbehenaat

Filmbedekking: Etielsellulose 100, povidoon, poliëtileenglikol 1450, metakrielsuur kopolimeer dispersie (Eudragit L30 D-55), silikoondioksied, triëtielsitraat, eetbare swart ink (vir drukwerk).

Suikervry.

WAARVOOR WELLBUTRIN XL GEBRUIK WORD:

WELLBUTRIN XL is ’n medisyne wat deur jou dokter voorgeskryf is om jou depressie te behandel. Daar word vermoed dat dit interaksie het met chemikalieë in die brein genaamd noradrenalien en dopamien wat met depressie geassosieer word.

Dit mag ’n rukkie neem voordat jy beter begin voel. Dit neem tyd, soms weke of maande, vir WELLBUTRIN XL om sy volle effek uit te oefen. Wanneer jy wel begin beter voel, mag jou dokter jou aanraai om steeds WELLBUTRIN XL te neem om te verhoed dat die depressie terugkeer.

Jou dokter het hierdie medisyne gekies om by jou en jou toestand te pas. Moenie dit vir ander mense gee nie. Voordat daar op behandeling met WELLBUTRIN XL besluit word, sal jy en jou dokter waarskynlik die risiko's en die voordele wat dit vir jou kan hê, bespreek. Hierdie brosjure sal jou help om WELLBUTRIN XL veilig te neem.

VOORDAT JY WELLBUTRIN XL NEEM:

Moenie WELLBUTRIN XL neem nie:

- indien jy weet dat jy vir WELLBUTRIN XL, bupropioon, of enige van die ander bestanddele in WELLBUTRIN XL tablette allergies is
- indien jy enige ander medisyne neem wat bupropioon bevat
- indien jy gediagnoseer is met epilepsie
- indien jy ’n eetversteuring het, of gehad het (bv. bulimie of anorexia nervosa)
- indien jy ’n besonder swaar drinker is en so pas alkohol gelos het of as jy amper op die punt is om drank te staak

- indien jy onlangs opgehou het om kalmeermiddels of sedatiewe te neem, of as jy hulle gaan staak terwyl jy WELLBUTRIN XL neem
- indien jy ander medisyne vir depressie, wat monoamienoksidase-inhibeerders (MAOIs) genoem word, in die afgelope 14 dae geneem het
- indien jy swanger is of borsvoed
- as jy jonger as 18 jaar oud is. Daar is ’n verhoogde risiko vir selfmoordgedagtes en -gedrag wanneer kinders onder die ouderdom van 18 jaar met antidepressante behandel word.

As enigeen van hierdie op jou van toepassing is, gesels dadelik met jou dokter sonder om WELLBUTRIN XL te neem.

Neem spesiale sorg met WELLBUTRIN XL:

Gesels met jou dokter voordat jy WELLBUTRIN XL neem:

- indien jy ooit stuipe of aanvalle in die verlede gehad het
- indien jy ’n gewas op die brein het
- indien jy lewer- of nierprobleme het
- indien jy gereeld baie alkohol drink
- indien jy diabetes het waarvoor jy insulien of tablette gebruik
- indien jy enige ander geestesversteuring, benewens depressie, al gehad het
- indien jy ’n ernstige kopbesering gehad het
- indien jy ouer as 65 jaar is
- indien jy swanger is of beplan om eersdaags swanger te word.

Indien enigeen van bogenoemde op jou van toepassing is, mag jou dokter spesiale aandag aan jou versorging wil gee, of ’n ander behandeling aanbeveel.

Gedagtes van selfmoord of verergering van jou toestand:

Indien jy depressief is, kan jy soms gedagtes van selfbeskadiging hê of dink dat jy sal selfmoord pleeg. Hierdie gedagtes mag toeneem wanneer jy begin om antidepressante te neem. Hierdie medisyne neem almal tyd om te begin werk - gewoonlik ongeveer twee weke, maar soms langer.

Jy sal meer geneig wees om so te dink:

- as jy in die verlede gedagtes van selfmoord of selfbeskadiging gehad het
- as jy onder die ouderdom van 25 jaar is.

Indien jy gedagtes van selfbeskadiging of selfmoord te eniger tyd het: Kry mediese raad so gou as moontlik (van ’n dokter of by ’n hospitaal).

Neem WELLBUTRIN XL met voedsel en drank:

Drink van alkohol: Sommige mense vind dat hulle meer sensitief vir alkohol is wanneer hulle WELLBUTRIN XL neem en jou dokter mag voorstel dat terwyl jy WELLBUTRIN XL neem, jy geen alkohol (bier, wyn of spiritualieë) drink nie of dat jy probeer om baie min te drink. Maar indien jy tans baie drink, moet jy nie skielik staak nie, omdat dit gevaarlik kan wees. Gesels met die dokter oor drink van alkohol voordat jy begin om WELLBUTRIN XL te neem.

Swangerskap en laktasie:

Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgkundige vir advies voor jy WELLBUTRIN XL neem.

Indien jy swanger is, of dink dat jy moontlik swanger mag wees, of indien jy beplan om swanger te word, moet jy nie WELLBUTRIN XL neem sonder om met jou dokter daaroor te

gesels nie. Studies het ’n verhoging in die risiko van geboortedefekte, veral hartdefekte, gerapporteer by babas wie se moeders WELLBUTRIN XL geneem het.

Bestuur en gebruik van masjienerie:

Indien WELLBUTRIN XL jou duiselig of lighoofdig maak, moet jy nie bestuur of enige gereedskap of masjiene hanteer nie.

Neem van ander medisyne saam met WELLBUTRIN XL:

Vertel altyd jou gesondheidsorgkundige indien jy enige ander medisyne neem. (Dit sluit aanvullende of tradisionele medisyne in.)

Indien jy ander medisyne vir depressie, wat monoamienoksidase-inhibeerders (MAOIs) genoem word, in die vorige 14 dae geneem het, moet jy jou dokter daarvan vertel sonder om WELLBUTRIN XL te neem.

Indien jy enige ander medisyne, kruie of vitamiene neem, insluitend produkte wat jy self gekoop het, moet jy jou dokter daarvan vertel. Hy of sy mag jou dosis WELLBUTRIN XL verander, of voorstel dat jy jou ander medikasies verander.

Sommige medisyne meng nie met WELLBUTRIN XL nie. Sommige daarvan mag die moontlikheid van stuipe of aanvalle verhoog. Ander medisyne mag die risiko van ander newe-effekte verhoog. Sommige voorbeelde word hierna gelys, maar dit is nie ’n volledige lys nie.

Daar mag ’n groter moontlikheid as gewoonlik van aanvalle (stuipe) wees:

- as jy medisyne neem wat aanvalle (stuipe) meer waarskynlik maak, bv. teofillien vir asma of longsiekte, tramadol ’n sterk pynstiller

- as jy kalmeermiddels of sedatiewe geneem het, of as jy dit gaan staak terwyl jy WELLBUTRIN XL neem
- as jy stimulante of ander medisyne neem om jou gewig of aptyt te beheer.

Indien enige van hierdie op jou van toepassing is, gesels dadelik met jou dokter voordat jy WELLBUTRIN XL neem.

Daar mag 'n groter moontlikheid as gewoonlik van ander newe-effekte wees:

- indien jy sekere ander medisyne vir depressie of ander geestesversteurings neem
- indien jy medisyne vir Parkinson se siekte (levodopa, amantadien of orfenadrien) neem
- indien jy medisyne neem wat vir epilepsie gebruik word (karbamasepien, fenitoïen, fenobarbitoon)
- indien jy siklofosfamied of ifosfamied neem, wat hoofsaaklik gebruik word om kanker te behandel
- indien jy tiklopidien of klopidogrel neem, wat hoofsaaklik gebruik word om beroerte te voorkom
- indien jy sekere betablokkeerders neem
- indien jy medisyne vir hartritme neem
- indien jy nikotien-kleefpleisters gebruik om jou te help om rook te staak.

Indien enige van hierdie op jou van toepassing is, gesels dadelik met jou dokter voordat jy WELLBUTRIN XL neem.

HOE OM WELLBUTRIN XL TE NEEM:

Neem altyd WELLBUTRIN presies volgens jou dokter se instruksies. Maak met jou dokter of apteker seker as jy onseker is.

Hoeveel geneem moet word:

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

Jou dokter mag jou dosis tot 300 mg een keer per dag verhoog indien jou depressie nie na etlike weke verbeter nie.

Neem jou dosis WELLBUTRIN XL vroeg in die oggend.

Moenie WELLBUTRIN XL meer as een keer per dag neem nie.

Jou dokter mag jou dosis verander:

- as jy lewer- of nierprobleme het
- as jy ouer as 65 jaar is.

Sluk die tablette heel in. Moenie dit kou, vergruis of verdeel nie - indien jy dit doen, sal die medisyne te vinnig in jou liggaam vrygestel word. As dit gebeur dan sal jy meer geneig wees om newe-effekte insluitend aanvalle (stuipe) te ontwikkel.

Neem WELLBUTRIN XL altyd presies volgens jou dokter se aanbevelings. Hierdie is die gebruiklike dosisse, maar jou dokter se raad is persoonlik vir jou bedoel. Praat met jou dokter of apteker as jy onseker is.

Hoe lank dit geneem moet word:

Slegs jy en jou dokter kan besluit hoe lank jy WELLBUTRIN XL moet neem. Dit mag weke of maande van behandeling verg voordat jy enige verbetering ervaar. Bespreek jou simptome gereeld met jou dokter om te besluit hoe lank jy dit behoort te neem. Wanneer jy

wel begin om beter te voel, mag jou dokter aanbeveel dat jy steeds aanhou om WELLBUTRIN XL te neem om te verhoed dat jou depressie weer terugkeer. Moenie WELLBUTRIN XL staak of jou dosis verminder, sonder om eers met jou dokter daaroor te gesels nie.
Soms het WELLBUTRIN XL tablette 'n ongewone reuk. Dit is normaal: gaan voort om die tablette soos gebruiklik te neem.

Indien jy meer WELLBUTRIN XL neem as wat jy moes:

Indien jy te veel tablette neem, kan jy die risiko van 'n aanval (stuipe) verhoog.
Ander ernstige effekte mag ook gebeur. **Moenie uitstel nie.** Vra jou dokter wat jy moet doen of kontak dadelik die noodafdeling van jou naaste hospitaal.

Indien jy vergeet om WELLBUTRIN XL te neem:

Indien jy 'n dosis oorslaan, wag en neem jou volgende tablet op die gebruiklike tyd. **Moenie 'n tablet neem om op te maak** vir die dosis wat jy vergeet het nie.

MOONTLIKE NEWE-EFFEKTE:

WELLBUTRIN XL mag newe-effekte veroorsaak.
Nie alle newe-effekte wat vir WELLBUTRIN XL aangemeld is, is in die brosjure ingesluit nie. Indien jou algemene gesondheid versleg of indien jy enige ongewenste effekte ervaar terwyl jy die medisyne neem, raadpleeg asseblief jou dokter, apteker of gesondheidsorgkundige vir advies.

Aanvalle (stuipe):

Ongeveer 1 uit elke 1 000 mense wat die maksimum dosis WELLBUTRIN XL neem, is aan die risiko van ’n aanval (stuipe) blootgestel. Die kans dat dit kan gebeur is hoër as jy te veel neem, as jy sekere medisyne neem in kombinasie met WELLBUTRIN XL, of as jy aan ’n groter risiko vir aanvalle (stuipe) as gewoonlik blootgestel is. Indien jy bekommerd is, gesels met jou dokter. Indien jy ’n aanval het, vertel jou dokter daarvan wanneer jy herstel het. Moenie meer tablette neem nie.

Allergies reaksies:

Sommige mense mag allergiese reaksies teenoor WELLBUTRIN XL ontwikkel. Dit sluit in:

- rooi vel of veluitslag (soos netelroos), blase of jeukerige bulte (galbulte) op die vel. Hospitaalbehandeling mag vir sommige veluitslae nodig wees, veral as jy ook ’n seer mond of seer oë het
- ongewone hyg of probleme met asemhaling
- geswolle ooglede, lippe of tong
- pyne in die spiere of gewrigte
- ineenstorting of floute.

Indien jy enige tekens van ’n allergiese reaksie het, moet jy dadelik ’n dokter kontak. Moenie meer tablette neem nie. Allergiese reaksies kan lank aanhou. Indien jou dokter iets voorskryf om te help met die allergiese simptome, moet jy seker maak dat jy die kursus voltooi.

Ander newe-effekte:

Versteurde slaap: Die mees algemene newe-effek by mense wat WELLBUTRIN XL neem, is probleme met slaap. Maak seker dat jy jou tablet vroeg in die oggend neem.

Ander algemene newe-effekte:

- hoofpyn, koors, duiseligheid, jeuk, sweet, veluitslag, galbulte
- bewerigheid, tremor, borspyn
- gevoel van angs of agitasie
- droë mond, maagpyn of ander probleme (naar gevoel, braking, hardlywigheid), veranderings in die smaak van kos, verlies aan aptyt
- veranderings in bloeddruk, blosing
- suisgeluide in die ore, visuele versteurings.

***Ongewone newe-effekte*:**

- swakheid, moegheid
- gevoel van depressie
- gevoel van verwarring
- probleme met konsentrasie
- verhoogde harttempo
- gewigsverlies.

***Die volgende newe-effekte mag voorkom*:**

- aanvalle (konvulsies)
- hartkloppings, floutes
- onbeheerde bewegings, spiertrekkings, spierstyfheid, probleme met stap of koördinasie
- gevoel van rusteloosheid, prikkelbaarheid, hostiliteit, aggressie of ’n paranoïese gevoel, gevoel van onwerklikheid of vreemdheid (depersonalisasie), voel of glo dinge wat nie

bestaan nie (hallusinasies/delusies), vreemde drome, prikkeling of gevoelloosheid, geheueverlies

- verhoogde lewerensieme, geel-wording van die vel of die wit deel van jou oë (geelsug), hepatitis
- ernstige allergiese reaksies; veluitslag saam met gewrig- en spierpyne
- veranderings in bloedsuikervlakke
- urineer meer of minder as gewoonlik.

Gesels met jou dokter of apteker oor enige hinderlike newe-effekte. Indien jy van enige newe-effekte bewus word wat nie in hierdie brosjure genoem word nie, moet jy asseblief jou dokter of apteker daarvan vertel.

Gedagtes van selfmoord of verergering van jou toestand:

Indien jy depressief is, kan jy soms gedagtes koester om jouself skade aan te doen of om selfmoord te pleeg. Hierdie gedagtes mag toeneem wanneer jy aanvanklik met antidepressante begin. Hierdie medisyne kan tyd neem om te begin werk - gewoonlik **ongeveer twee weke, maar soms langer (sien 'Neem spesiale sorg met WELLBUTRIN XL').**

Kinders jonger as 18 jaar:

WELLBUTRIN XL behoort nie gebruik te word om kinders jonger as 18 jaar te behandel nie. Daar is 'n verhoogde risiko van selfmoordgedagtes en -gedrag as kinders onder 18 jaar met antidepressante behandel word.

BERGING EN WEGDOENING VAN WELLBUTRIN XL:

Hou buite bereik en sig van kinders.

Bewaar by of benede 25 °C. Hou dig gesluit.

Bewaar in die oorspronklike verpakking, weg van direkte sonlig.

Moenie na die vervaldatum wat op die buitenste verpakking gestempel is, gebruik nie.

Indien jy enige WELLBUTRIN XL oor het nadat jou behandeling voltooi is, neem dit terug na die apteker.

AANBIEDING VAN WELLBUTRIN XL:

WELLBUTRIN XL 150: Wit ondeurskynende plastiek HDPE bottels met wit polipropileen plastiek kinderbestande sluitings, wat 30 tablette bevat.

WELLBUTRIN XL 300: Wit ondeurskynende plastiek HDPE bottels met wit polipropileen plastiek kinderbestande sluitings, wat 30 tablette bevat.

IDENTIFIKASIE VAN WELLBUTRIN XL:

WELLBUTRIN XL 150: Roomkleurige wit tot ligte geel, ronde tablet met ‘GS5FV’ op een kant in swart ink gedruk, terwyl die ander kant onversier is.

WELLBUTRIN XL 300: Roomkleurige wit tot ligte geel, ronde tablet met ‘GS5YZ’ op een kant in swart ink gedruk, terwyl die ander kant onversier is.

REGISTRASIENOMMER:

WELLBUTRIN XL 150: 41/1.2/0371

WELLBUTRIN XL 300: 41/1.2/0372

NAAM EN ADRES VAN REGISTRASIEHOUER:

GlaxoSmithKline South Africa (Edms) Bpk

Hawkinslaan 39

Epping Industrie 1, 7460

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