PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

BUPROPION 150 / 300 XL DRL extended-release tablets

Bupropion hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking BUPROPION XL DRL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- BUPROPION XL DRL 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 is in this leaflet

1. What BUPROPION XL DRL is and what it is used for
2. What you need to know before you take BUPROPION XL DRL
3. How to take BUPROPION XL DRL
4. Possible side effects
5. How to store BUPROPION XL DRL
6. Contents of the pack and other information

1. What BUPROPION XL DRL is and what it is used for

BUPROPION XL DRL is a medicine prescribed by your doctor to treat your depression. It is 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 BUPROPION XL DRL to have its full effect, sometimes weeks or months.

When you do start feeling better, your doctor may advise you to keep taking BUPROPION XL DRL 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 BUPROPION XL DRL, 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 BUPROPION XL DRL safely.

2. What you need to know before you take BUPROPION XL DRL

Do not take BUPROPION XL DRL:

- if you are hypersensitive (allergic) to bupropion or any of the other ingredients of BUPROPION XL DRL (listed in section 6).
- if you are taking 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 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 BUPROPION XL DRL
- if you have been taking other medicines for depression called monoamine oxidase inhibitors (MAOIs) in the last 14 days

- if you have severe liver problems
- 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 you are a woman of child-bearing potential not using contraception.

If any of these applies to you, talk to your doctor straight away, without taking BUPROPION XL DRL.

Warnings and precautions

Take special care with BUPROPION XL DRL:

Talk to your doctor before taking BUPROPION XL DRL

- 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 have a heart disease
- if you suffer from high blood pressure
- if you are taking medicines for depression. The use of these medicines together with *BUPROPION XL DRL* can lead to serotonin syndrome, a potentially life-threatening condition (see "*Other medicines and BUPROPION XL DRL"* in this section)

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

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

Thoughts of suicide or worsening of your condition:

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

You may be more likely to think like this:

- if you have previously had thoughts about killing or harming yourself
- if you are under 25 years of age

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.

BUPROPION XL DRL tablets should only be taken orally.

Swallow the tablet whole. Do not inhale crushed tablets or inject dissolved tablets – if you do, the medicine will be released into your body too quickly. If this happens you may overdose and be more likely to get side effects.

Seizures (fits) and/or death have occurred when BUPROPION XL DRL has been given intra-nasally or by injection.

Serotonin syndrome:

BUPROPION XL DRL may interact with some medicines (i.e. serotonergic agents) used for the treatment of depression, leading to a potentially life-threatening condition called serotonin syndrome.

You may experience mental status changes (e.g. agitation, hallucinations, coma), and other effects, such as body temperature above 38 °C, increase in heart rate, unstable blood pressure, and exaggeration of reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea).

Other medicines and BUPROPION XL DRL

Always tell your healthcare provider if you are taking any other medicine.

(This includes all 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 BUPROPION XL DRL.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, herbs or vitamins, including medicines you bought without a prescription. He or she may alter your dose of BUPROPION XL DRL or suggest a change in your other medicines.

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

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

- if you take medicines which make seizures (fits) more likely, e.g. theophylline for asthma or lung disease, tramadol as a strong painkiller
- if you take medicines to treat diabetes such as insulin or other medicines to lower your blood sugar
- if you have been taking tranquillisers or sedatives, or if you are going to stop them while you're taking BUPROPION XL DRL
- if you take stimulants or other medicine to control your weight or appetite

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

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 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 you take ritonavir or efavirenz, medicines used to treat HIV infection.

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

BUPROPION XL DRL may make other medicines less effective:

- if you take tamoxifen used to treat breast cancer
- if you take digoxin for your heart, tell your doctor. Your doctor may consider adjusting the dose of digoxin.

BUPROPION XL DRL with food, drink, and alcohol

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

Effect on urine tests

BUPROPION XL DRL may interfere with some urine tests to detect other drugs. If you require a urine test, tell your doctor that you are taking BUPROPION XL DRL.

Pregnancy, breastfeeding and fertility

You should not take BUPROPION XL DRL if you are pregnant, as safety in pregnancy has not been established. Studies have reported an increase in the risk of birth defects, particularly heart defects, in babies whose mothers were taking bupropion hydrochloride.
You should not breastfeed while taking BUPROPION XL DRL.
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 this medicine.

Driving and using machines

It is not always possible to predict to what extent BUPROPION XL DRL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the

above activities until they are aware of the measure to which BUPROPION XL DRL affects them.

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

3. How to take BUPROPION XL DRL

Do not share medicines prescribed for you with any other person.

Always take BUPROPION XL DRL exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

The usual starting dose for adults is 150 mg taken as a single daily dose in the morning.

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

There should be an interval of at least 24 hours between successive doses.

Take your dose of BUPROPION XL DRL early in the morning.

Do not take BUPROPION XL DRL 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 tablet whole. Do no chew, crush 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 BUPROPION XL DRL 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:

Your doctor will tell you how long your treatment with BUPROPION XL DRL will last.

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 BUPROPION XL DRL to prevent depression coming back.

Do not stop treatment early or reduce your dose without talking to your doctor first. If you have the impression that the effect of BUPROPION XL DRL is too strong or too weak, tell your doctor or pharmacist.

If you take more BUPROPION XL DRL than you should

If you take too many tablets, you may increase the risk of a seizure (fit) and other serious side effects such as loss of consciousness and effects on the heart.

Immediately consult your doctor or pharmacist. If neither is available, contact the nearest hospital emergency department at once.

If you forget to take BUPROPION XL DRL

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

Do not take a double dose to make up for the dose you forgot.

4. Possible side effects

BUPROPION XL DRL can have side effects.

Not all side effects reported for BUPROPION XL DRL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BUPROPION XL DRL, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking BUPROPION XL DRL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- fits (seizures)
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- allergic reactions such as rash or itching or blisters on the skin
- feeling lightheaded or faint

These are all very serious side effects. If you have them, you may have had a serious reaction to BUPROPION XL DRL. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- hypersensitivity reactions such as urticaria (hives, itchy rash)
- anorexia (an eating disorder characterized by weight loss)
- difficulty falling or staying asleep (insomnia)
- feeling anxious or agitated
- headache
- uncontrollable shaking
- dizziness
- changes in taste
- change to vision
- noise or ringing in the ear
- increased blood pressure (sometimes severe)
- flushing

- dry mouth
- ailments of the digestive system such as nausea and vomiting
- stomach pain
- constipation
- skin rash
- itchy skin
- sweating
- fever
- abnormal physical weakness or lack of energy
- chest pain

Less frequent side effects

- painless swelling under the skin (angioedema)
- shortness of breath
- severe, potentially life-threatening allergic reaction (anaphylactic shock)
- joint pain
- muscle pain
- fever

These symptoms may resemble serum sickness, an immune response that is similar to an allergic reaction

- abnormality in blood sugar stability
- weight loss
- confusion and/or depression
- feeling restless

- feeling aggressive, hostile, or irritable
- hallucinations
- abnormal dreams
- feeling unreal or strange
- delusions (can't tell what's real from what is imagined)
- thinking is dominated by suspicious content such as being spied on or followed
- concentration disturbance
- fits (seizures)
- uncontrolled movements (dystonia)
- problems with walking or coordination (ataxia)
- parkinsonism, a disorder of the central nervous system that affects movement, often including tremors
- lack of coordination
- loss of memory
- pins-and-needles sensation
- fainting
- rapid heartbeat
- palpitations (heartbeats that suddenly become more noticeable)
- widening of blood vessels, which can cause inflamed areas of the body to appear red or feel warm
- postural hypotension (low blood pressure in which a person becomes dizzy, lightheaded or faints, when standing up from sitting or lying down)

- high level of liver enzymes
- yellow discoloration of the skin and whites of the eyes (jaundice)
- inflammation of the liver (hepatitis)
- erythema multiforme, a skin disorder characterised by bull's-eye-shaped lesions
- Stevens-Johnson syndrome a rare, serious disorder of the skin and mucous membranes
- worsening of thick or red, scaly skin patches
- twitching
- urinating more or less than usual, or loss of bladder control

Side effects with unknown frequency:

- low blood sodium
- thinking and talking about suicide
- Psychosis, a condition that affects the way your brain processes information, and causes you to lose touch with reality
- Serotonin syndrome, a condition where you may experience mental status changes (e.g. agitation, hallucinations, coma), and other effects, such as body temperature above 38 °C, increase in heart rate, unstable blood pressure, and exaggeration of reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea).

If you notice any side effects not mentioned in this leaflet, please inform 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 BUPROPION XL DRL).

Children under 18 years of age:

BUPROPION XL DRL 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, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of BUPROPION XL DRL.

5. How to store BUPROPION XL DRL

Keep out of reach and sight of children.

Store at or below 25 °C

Keep container well closed.

Do not store in a bathroom.

Do not use after the expiry date stated on the label / carton / bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BUPROPION XL DRL contains

- The active substance is bupropion hydrochloride.
- The other ingredients are:

  Copovidone, microcrystalline cellulose, hypromellose, hydrochloric acid,

  colloidal silicon dioxide, talc, magnesium stearate

  Film-coat: Opadry II, methacrylic acid copolymer dispersion (Eudragit L30 D-55), silicon dioxide, triethyl citrate

  Opadry II Clear: Polyvinyl alcohol, talc, macrogol/PEG polysorbate 80

What BUPROPION XL DRL looks like and contents of the pack

BUPROPION 150 XL DRL: White to pale yellow, round, biconvex film-coated tablet, debossed with '144' on one side and plain on the other side.

BUPROPION 300 XL DRL: White to pale yellow, modified capsule shape, biconvex, film-coated tablet, debossed with '145' on one side and plain on other side.

BUPROPION 150 XL DRL: White HDPE bottles with white polypropylene child-resistant closure and a desiccant, containing 30 tablets.

BUPROPION 300 XL DRL: White HDPE bottles with white polypropylene child-resistant closure and a desiccant, containing 30 tablets.

Registration numbers

BUPROPION 150 XL DRL: 56/1.2/0292

BUPROPION 300 XL DRL: 56/1.2/0293

Holder of Certificate of Registration

Dr Reddy's Laboratories (Pty) Ltd

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Access to the corresponding Professional Information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories (Pty) Ltd. website: http://www.drreddys.co.za

For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration:

Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100

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