PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S5

[PRODYNA] 150 mg XR extended-release tablets

[PRODYNA] 300 mg XR extended-release tablets

Bupropion hydrochloride

Sugar free.

Read all of this leaflet carefully before you start taking [PRODYNA]

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- [PRODYNA] 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 [PRODYNA] is and what it is used for

[PRODYNA] contains bupropion, one of a group of medicines called antidepressants.

[PRODYNA] is a medicine to treat your depression.

2. What you need to know before you take [PRODYNA]

Do not take [PRODYNA]:

- if you are hypersensitive (allergic) to bupropion or any of the other ingredients of [PRODYNA] (see section 6)
- if you are under 18 years old
- if you suffer from fits or seizures
- if you are taking any medicine which already contains bupropion hydrochloride
- if you have abruptly stopped drinking alcohol or using sedatives
- if you have or had been diagnosed with the eating disorders bulimia (binge eating followed by making yourself vomit) or anorexia (abnormal low body weight with an intense fear of gaining weight)
- if you are taking a medicine which is a monoamine oxidase inhibitor (MAOI) (antidepressants)
- if you have a liver disease.

Warnings and precautions

Take special care with [PRODYNA]:

Seizures:

You should not exceed the dose of [PRODYNA] as prescribed by your doctor as the risk of seizures increases.

Your risk of seizures also increases in the following situations, therefore inform your doctor if any of the below pertains to you:

- if you've ever had any fits or seizures
- if you have ever had a serious head injury
- if you have a brain tumour
- if you are taking medicine for seizures
- if you have diabetes for which you use insulin or tablets
- if you regularly drink a lot of alcohol
- if you have had any mental illness other than depression, including eating

disorders.

If you experience a seizure (fit) whilst during treatment, stop taking [PRODYNA] and contact your doctor immediately.

***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).

You should talk to your doctor, especially if:

- you have uncontrolled coronary artery disease (a heart disease caused by poor blood flow in the blood vessels of the heart) with symptoms such as angina (characterised by chest pain) or a recent heart attack
- if you have liver or kidney problems
- you have a history of mania (feeling elated or over-excited, which causes unusual behaviour)
- if you are elderly.

Children and adolescents

[PRODYNA] should not be used in children and adolescents below 18 years.

Other medicines and [PRODYNA]

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

Your doctor may alter your dose of [PRODYNA] or suggest a change in your other medicines.

Do not take [PRODYNA] with:

- **Monoamine oxidase inhibitors** (medicines to treat depression or Parkinson's disease) such as phenelzine, selegiline, or rasagiline. You must stop taking these medicines for at least 14 days before starting [PRODYNA] (see Do not take [PRODYNA]).

Tell your doctor if you are taking any of the following medicines, as your doctor will closely monitor you for side effects:

- orphenadrine (to treat muscle cramps), cyclophosphamide and ifosfamide (to treat certain types of cancer), ticlopidine (used to reduce the risk of a stroke), clopidogrel (used to reduce the risk of heart disease and stroke)
- medicines which make seizures (fits) more likely e.g. theophylline for asthma or lung disease, tramadol a strong painkiller

- anti-depressants, tranquillisers or sedatives, e.g. citalopram, desipramine, amitriptyline, fluoxetine, sertraline, or any other medicine for depression or mental illness, or if you are going to stop them while you're taking [PRODYNA]
- medicine for high blood pressure or heart disease (beta-blockers or anti-dysrhythmics), e.g. propranolol, amiodarone
- medicine called ritonavir used to treat HIV
- medicine to treat Parkinson's disease that contains levodopa or amantadine
- medicines used to treat epilepsy such as carbamazepine, phenytoin or phenobarbitone
- stimulants or medicine used for lowering your appetite
- nicotine patches to stop smoking.

Talk to your doctor or pharmacist before taking PRODYNA:

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

[PRODYNA] with food, drink and alcohol

Excessive use of alcohol while being treated with [PRODYNA] might increase the risk for fits (seizures), mental disorder events or might reduce alcohol tolerance. Your doctor may suggest you do not drink alcohol while you are taking [PRODYNA] or try to drink as little as possible. If you do drink a lot now, do not just stop suddenly, because that may put you at risk of having a fit.

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 healthcare provider for advice before using [PRODYNA].

Studies have reported an increase in the risk of birth defects, particularly heart defects, in babies whose mothers were taking [PRODYNA]. Thus [PRODYNA] should not be used during pregnancy, or while breastfeeding.

Driving and using machines

[PRODYNA] may make you dizzy or light-headed.
It is not always possible to predict to what extent [PRODYNA] may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which [PRODYNA] affects you.

3. How to take [PRODYNA]

Do not share medicines prescribed for you with any other person.
Always use [PRODYNA] exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Adults:

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 [PRODYNA] early in the morning.

Do not take [PRODYNA] 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).

Your doctor will tell you how long your treatment with [PRODYNA] will last. Do not stop treatment early because your depression may return.

If you have the impression that the effect of [PRODYNA] is too strong or too weak, tell your doctor or pharmacist.

If you take more [PRODYNA] than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose may include:

- drowsiness, loss of consciousness, irregular heartbeat.

If you forget to take/use [PRODYNA]

If you forget to take [PRODYNA], take a dose as soon as you remember, then continue to take [PRODYNA] at the usual times. Do not take a double dose to make up for forgotten individual doses.

If you stop taking [PRODYNA]

It is important that you continue the course of treatment even if you begin to feel better after a few days. If you suddenly stop taking this medicine, the depression symptoms may come back or unwanted effects such as fits may appear.

4. Possible side effects

[PRODYNA] can have side effects.

Not all side effects reported for [PRODYNA] are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using [PRODYNA], please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using [PRODYNA] and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- seizures, fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to [PRODYNA]. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- uneven heartbeat (palpitations), increased, irregular or fast heartbeat (tachycardia), heart attack, stroke
- mood changes or mood swings or changes in personality, confusion, depression, aggression, delusions, abnormal behaviour
- thinking about or feeling like killing yourself, suicide attempt
- hallucinations (hearing voices or seeing things which are not there), believing things that are not true or being suspicious
- sudden chest pain due to blood clots in your lungs
- Stevens Johnson Syndrome (a rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals)
- yellowing of the skin and eyes, also called jaundice and inflammation of the liver.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- hypersensitivity reactions like hives
- anorexia/lack of appetite, weight loss
- insomnia (sleep disorder), agitation, anxiety
- headache, tremor, dizziness, taste disorders
- vision disorders, ringing or buzzing in the ears
- high blood pressure, flushing (hot flush)
- dry mouth, nausea, vomiting, abdominal pain, constipation
- rash, itching, sweating
- fever, chest pain, lack of energy

Less frequent side effects:

- blood glucose disturbances
- confusion, depression, aggression, feelings of opposition, unkindness or unfriendliness toward something or someone, irritability, restlessness, abnormal dreams
- unable to concentrate, unable to control muscle movements leading to abnormal walk, speech and abnormal eye movements, coordination problems, Parkinsonism (a disorder of the central nervous system that affects movement, often including tremors), loss of memory, “pins and needles”

- a form of low blood pressure that happens when standing up from sitting or lying down
- a skin reaction that can be triggered by an infection or some medicines
- blood tests showing increased level of liver enzymes
- twitching
- need to urinate often or unable to urinate

The following side effects have been reported but the frequency for them to occur is not known:

- bruising, reduction in red blood cells which can make the skin pale and cause weakness or breathlessness, increase in number of white blood cells, low white blood cell count, enlargement of lymph node, severe reduction in blood cells which can cause weakness, bruising or make infections more likely, reduction in blood platelets, which increases risk of bleeding or bruising
- bleeding into the tissues, bruising, and slow blood clotting after injury
- too much or too little glucose in the bloodstream, a condition in which the body makes too much antidiuretic hormone (ADH) – a hormone that helps the kidneys control the amount of water your body loses through the urine
- excess of sugar in the urine

- mood changes where strong emotions or feelings (uncontrollable laughing or crying or feeling very irritable or temper) occur, feeling detached from your surroundings
- problems with walking or coordination, muscle spasm, too much muscle tone, sensitivity of any of your senses, such as sight, sound, touch, and smell, feeling off-balance (vertigo), memory loss, abnormal electrical activity in the brain as measured by an EEG (electroencephalogram), loss of voluntary movement, speech impairment or slurred speech, coma, uncontrolled involuntary muscle movement, increased sexual desire, slow movement, stabbing, burning, and often severe pain due to an irritated or damaged nerve
- damage to the nerves which can cause numbness, pain and weakness, involuntary, repetitive body movements including grimacing, sticking out the tongue, or smacking the lips
- difficulty in sight when changing focus from far objects to nearby objects, dry eyes, increase in pressure in the eye, dilated pupils
- deafness
- high blood pressure, vein inflammation
- tight chest, lung infection
- heartburn, mouth sores, inflammation of the mouth, thirst, inflammation of your colon which causes abdominal pain or diarrhoea, inflammation of the tube running from your throat to your stomach, bleeding in the stomach and intestines, tear in intestines, stomach ulcer

- abnormal liver function, liver damage, inflammation of the pancreas, which causes severe pain in the abdomen and back
- red area on the skin that is covered with small merging bumps, hair loss, painless swelling under the skin, redness and peeling of the skin over large areas of the body, abnormal hair growth
- leg cramps, fever, abnormal muscle breakdown which can lead to kidney problems, muscle weakness
- pain/discomfort when urinating, leakage of urine, bladder infection
- inability in a man to achieve an erection or orgasm, prostate problems, discharge of semen, difficult or painful sexual intercourse, enlarged breasts in males, menopause, painful erection, inflammation of the fallopian tubes, inflammation of the vagina that can result in discharge, itching and pain
- a condition in which you grind, gnash or clench your teeth, red, swollen and inflamed tongue, gum disease, increase in saliva, sores in mouth, swelling of tongue, bleeding of the gums.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report any side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of [PRODYNA]. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store [PRODYNA]

Store all medicines out of reach of children.

Store at or below 25 °C in original container.

Do not use after the expiry date stated on the carton.

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 [PRODYNA] contains

The active substance is bupropion hydrochloride.

Each [PRODYNA] 150 mg XR tablet contains 150 mg bupropion hydrochloride.

Each [PRODYNA] 300 mg XR tablet contains 300 mg bupropion hydrochloride.

The other ingredients are:

Cores: glyceryl behenate, hydrophobic colloidal silica, L-cysteine hydrochloride monohydrate, polyvinyl alcohol.

Coating: colloidal silicon dioxide, dibutyl sebacate, ethyl cellulose, hydroxypropyl cellulose, methacrylic acid copolymer dispersion, povidone, triethyl citrate.

The imprinting contains: **Opacode black:** Ammonium hydroxide, iron oxide black, isopropyl alcohol, N-butyl alcohol, propylene glycol, shellac glaze.

[PRODYNA] is sugar free.

What [PRODYNA] looks like and contents of the pack

[PRODYNA] 150 mg XR: Off-white to pale yellow, round, biconvex, coated tablets, imprinted with “L015” in black ink on one side and plain on other side.

[PRODYNA] 300 mg XR: Off-white to pale yellow, round, biconvex, coated tablets, imprinted with “L016” in black ink on one side and plain on other side.

[PRODYNA] is packed into:

150 mg:

30's: White opaque 100 mL HDPE bottle containing 30 tablets along with one molecular sieve 1 g sachet, one activated carbon 1 g sachet and one StabilOx® strip form sachet closed with white child resistant closure.

90's: White opaque 150 mL HDPE bottle containing 90 tablets along with one molecular sieve 1 g sachet, one activated carbon 1 g sachet and one StabilOx® strip form sachet closed with white child resistant closure.

500's: White opaque 500 mL HDPE bottle containing 500 tablets along with one molecular sieve 5 g sachet, one activated carbon 5 g sachet and one StabilOx® strip form sachet closed with white non child resistant closure.

300 mg:

30's: White opaque 100 mL HDPE bottle containing 30 tablets along with one molecular sieve 1 g sachet, one activated carbon 1 g sachet and one StabilOx® strip form sachet closed with white child resistant closure.

90's: White opaque 250 mL HDPE bottle containing 90 tablets along with one molecular sieve 1 g sachet, one activated carbon 1 g sachet and one StabilOx® strip form sachet closed with white child resistant closure.

500's: White opaque 500 mL HDPE bottle containing 500 tablets along with one molecular sieve 5 g sachet, one activated carbon 5 g sachet and one StabilOx® strip form sachet closed with white non child resistant closure.

Holder of Certificate of Registration

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