Applicant: Teva Pharmaceuticals (Pty) Ltd	Product name: BUPYRA XL 150 & 300
Registration numbers: BUPYRA XL 150: 54/1.2/0026 BUPYRA XL 300: 54/1.2/0533	Dosage form & strength: Each extended release tablet contains 150 mg or 300 mg bupropion hydrochloride

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS: S5

BUPYRA XL 150, extended release tablets

BUPYRA XL 300, extended release tablets

Bupropion hydrochloride

Sugar free.

Read all of this leaflet carefully before you start taking BUPYRA XL:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- **BUPYRA 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 IS IN THIS LEAFLET:

1. WHAT BUPYRA XL IS AND WHAT IT IS USED FOR:

BUPYRA XL 150 contains 150 mg bupropion hydrochloride per extended release tablet.

BUPYRA XL 300 contains 300 mg bupropion hydrochloride per extended release tablet.

BUPYRA XL 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.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BUPYRA XL:

Do not take BUPYRA XL:

- If you are hypersensitive (allergic) to bupropion hydrochloride or any of the other ingredients of **BUPYRA XL**.
- If you are younger than 18 years of age.
- If you have been diagnosed with epilepsy or have a history of seizures.
- If you have a brain tumour.
- If you are taking any other medicines which contain bupropion.
- If you are usually a heavy drinker or taking any sedatives and recently stopped or plan to suddenly stop drinking or taking sedatives.
- If you have an eating disorder, or used to (for example, bulimia or anorexia nervosa).
- If you are taking or have been taking other medicines for depression called monoamine oxidase inhibitors (MAOIs) in the last 14 days.
- If you have severe liver problems.

Warnings and precautions:

Take special care with BUPYRA XL:

- If you have had a serious head injury or a history of head trauma.
- If you have had a brain tumour.
- If you have diabetes for which you use insulin or tablets.
- If you are a heavy drinker or if you are using any sleeping pills (see also **Do not take BUPYRA XL**).

- **BUPYRA XL** has been shown to have an increased risk to cause fits (seizures). This side effect is more likely to occur in people from the groups listed above. If you have a fit during treatment you should stop taking **BUPYRA XL**. Do not take any more and see your doctor.
- If you have heart problems.
- If you have severe liver problems.
- If you have kidney problems.

Thoughts of suicide and worsening of your depression:

If you are depressed, you can sometimes have thoughts of harming or killing yourself. These symptoms may worsen when **BUPYRA XL** treatment is started, since it takes time to work, or when your dosage is increased or decreased. You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

  If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.
- If you have a bipolar disorder (extreme mood swings), as **BUPYRA XL** could bring on an episode of this illness.
- If you previously experienced an allergic reaction towards **BUPYRA XL** or experience an allergic reaction during treatment, the treatment should be stopped and treatment for the allergic reaction should be initiated.
- If you have high blood pressure or if you are using nicotine transdermal patches, your blood pressure should be monitored while taking **BUPYRA XL**.
- If you need to take a urine drug test, inform your healthcare provider that you are taking **BUPYRA XL**.
- **BUPYRA XL** should only be taken orally.

Children and adolescents:

BUPYRA XL is not recommended 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.

Other medicines and BUPYRA XL:

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

Tell your doctor if you are taking any of the following medicines:

- Antidepressants called monoamine oxidase inhibitors (MAOIs) in the last 14 days (see also **Do not take BUPYRA XL**).

Some medicines don't mix with **BUPYRA XL**. Some of them may increase the chance of fits or seizures. Other medicines may increase the risk of other side effects. Some examples are listed below, but it is not a complete list.

There may be a higher than usual chance of seizures:

- If you take other medicines for depression or other mental illness
- If you take theophylline for asthma or lung disease
- If you take tramadol, a strong painkiller
- If you take medicines against malaria (such as mefloquine or chloroquine)
- If you take steroids (by mouth or injection)
- If you take antibiotics called quinolones
- If you take some types of anti-histamines that can cause sleepiness
- If you have been taking sedatives, or if you are going to stop them while you're taking **BUPYRA XL** (see also **Do not take BUPYRA XL)**
- If you take medicines for diabetes
- If you take stimulants or other medicines to control your weight or appetite.

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

- If you take other medicines for depression (such as amitriptyline, fluoxetine, paroxetine, dosulepin, desipramine or imipramine) or other mental illness (such as clozapine, risperidone, thioridazine or olanzapine).
- If you take some beta blockers (such as metoprolol)
- If you take some medicines for irregular heart rhythm (propafenone or flecainide)
- If you take some medicines used to treat cancer (such as cyclophosphamide, ifosfamide)
- If you take ticlopidine or clopidogrel, mainly used to prevent stroke
- If you take medicines that affect your body's ability to breakdown **BUPYRA XL** (carbamazepine, phenytoin, valproate)
- If you take medicines for Parkinson's disease (levodopa, amantadine or orphenadrine)
- If you use nicotine patches to help you stop smoking.

BUPYRA XL may be less effective:

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

If this applies to you, tell your doctor. Your doctor will check how well **BUPYRA XL** is working for you. It may be necessary to increase your dose or change to another treatment for your depression. Do not increase your **BUPYRA XL** dose without advice from your doctor, as this may increase the risk of you having side effects, including seizures.

BUPYRA XL may make other medicines less effective:

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

BUPYRA XL with alcohol:

Alcohol can affect the way **BUPYRA XL** works and, when used together can rarely affect your nerves or your mental state. Some people find they are more sensitive to alcohol when taking **BUPYRA XL**. Your doctor may suggest you do not drink alcohol (beer, wine or spirits) while taking **BUPYRA XL**, or try to drink very little. But if you drink a lot now, do not stop suddenly: it may put you at risk of having a fit.

Talk to the doctor about drinking before you start taking **BUPYRA XL**.

Effect on urine tests:

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

Taking BUPYRA XL with food and alcohol:

BUPYRA XL can be taken with or without food. Do not take alcohol while taking **BUPYRA XL** (see also **Other medicines and BUPYRA XL**).

Pregnancy, breastfeeding and fertility:

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

Driving and using machines:

It is not always possible to predict to what extent **BUPYRA XL** 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 **BUPYRA XL** affects you.

3. HOW TO TAKE BUPYRA XL:

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

Always take **BUPYRA XL** exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

The usual dose is 150 mg taken as a single daily dose.

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

Take your dose of **BUPYRA XL** tablets in the morning. Do not take **BUPYRA XL** more than once each day.

The tablet is covered by a shell that slowly releases medicine inside your body. You may notice something in your stool that looks like a tablet. This is the empty shell passing from your body.

You should swallow the tablet whole. The tablets should not be cut, crushed or chewed.

Your doctor will tell you how long your treatment with **BUPYRA XL** will last. It may take weeks or months of treatment for you to see any improvement in your symptoms and your symptoms might even worsen when **BUPYRA XL** is started. Do not stop treatment early.

If you have the impression that the effect of **BUPYRA XL** is too strong or too weak, tell your doctor or pharmacist.

If you take more BUPYRA XL 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.

If you forget to take a dose of BUPYRA XL:

Do not take a double dose to make up for forgotten individual doses.

At least 24 hours should pass between each dose.

4. POSSIBLE SIDE EFFECTS:

BUPYRA XL can have side effects.

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

If any of the following happens, stop taking **BUPYRA XL** 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 and anaphylactic shock.
- 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. Pains in muscles or joints and fever have also been reported in association with rash and other symptoms suggestive of delayed hypersensitivity. Unusual wheezing or difficulty in breathing.
- Fainting.
- Yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **BUPYRA XL**. 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:

Less frequent:

- fast, strong and irregular heartbeat
- flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters that may affect the mouth and other parts of the body and can be life-threatening.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- eating disorder (anorexia)
- difficulty in sleeping

- feeling agitated
- feelings of worry
- headache
- shakiness
- dizziness
- taste disturbance
- visual disturbances
- ringing in the ears (tinnitus)
- increase in blood pressure sometimes severe, flushing
- dry mouth
- feeling sick, vomiting
- stomach upset, stomach pain
- constipation
- sweating
- fever
- chest pain
- lack of energy

Less frequent side effects:

- weight loss
- blood glucose disturbances
- depression
- feeling confused
- unfriendliness
- feeling irritable
- restlessness

- seeing or hearing things that are not there (*hallucinations*)
- strange dreams; sensing or believing things that are not true (*delusions*)
- feeling unreal or strange (*depersonalisation*); severe suspiciousness (*paranoia*)
- difficulty concentrating
- uncontrolled movements, problems with walking or coordination
- parkinsonism
- memory impairment
- seizures
- an abnormal sensation, typically tingling or pricking ('pins and needles'), (*paraesthesia*)
- vasodilation which decrease blood pressure
- falling of blood pressure when suddenly standing up from a lying or sitting position
- increased liver enzymes
- inflammation of the liver (hepatitis)
- severe skin reactions
- exacerbation of psoriasis
- twitching
- urinating more or less than usual
- urinary incontinence (involuntary urination, leakage of urine)

Side effects with unknown frequency:

- reduced numbers of red blood cells (anaemia), reduced numbers of white blood cells (leucopenia) and reduced numbers of platelets (thrombocytopenia)
- decreased blood sodium (hyponatraemia)
- thoughts of harming or killing themselves
- loss of contact with reality and unable to think or judge clearly (psychosis).

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. This includes any possible side effects not listed in this leaflet. 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 this medicine.

5. HOW TO STORE BUPYRA XL:

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

BUPYRA XL 150: Store at or below 30 °C.

BUPYRA XL 300: Store at or below 25 °C.

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

Keep the bottle tightly closed.

Shelf life:

BUPYRA XL 150: Unopened: 2 years. After first opening: 2 months.

BUPYRA XL 300: 3 years.

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 BUPYRA XL contains:

BUPYRA XL 150: Each extended release tablet contains 150 mg bupropion hydrochloride.

The other ingredients are:

Core: hydroxypropyl cellulose, magnesium stearate, silicified microcrystalline cellulose, stearic acid 50.

Extended release coating: Opadry white 29A18501 consisting of: ethyl cellulose, hydroxypropyl cellulose, titanium dioxide (E171), triethyl citrate.

Modified release coating: methacrylic acid - ethyl acrylate copolymer, talc.

BUPYRA XL 300: Each extended release tablet contains 300 mg bupropion hydrochloride.

The other ingredients are:

Core: povidone, cysteine hydrochloride monohydrate, colloidal anhydrous silica, glycerol dibehenate, magnesium stearate.

First Coating: ethyl cellulose, povidone, macrogol.

Second coating: methacrylic acid - methyl methacrylate copolymer (1:1), colloidal hydrated silica, macrogol, triethyl citrate.

What BUPYRA XL looks like and contents of the pack:

Extended release tablets.

BUPYRA XL 150 is a round, biconvex creamy white to pale yellow extended release tablet.

BUPYRA XL 300 is a creamy-white to pale yellow, round tablet printed with "GS2" on one side and plain on the other side.

Packaging material and pack size:

BUPYRA XL 150: White, round, 75 ml HDPE containers with desiccant in canister and closed with child-resistant white plastic cap (PP-closure) that includes an induction heat seal membrane. The HDPE bottle will be packed in an outer carton box.

Pack sizes: 30, 60 or 90 tablets.

BUPYRA XL 300: Blister: OPA/Alu/PVC-Alu blister strips containing 7, 10, 14, 15 or 28 tablets per blister strip. The blister strips will be packed in an outer carton.

Pack sizes: 7, 28, 30, 56, 60 and 90 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration:

Teva Pharmaceuticals (Pty) Ltd.

Maxwell Office Park

Magwa Crescent West

Waterfall City

Midrand

Gauteng

2090

Tel: +27 (0)11 055 0200

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