PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S5

BUDEP XR 150 extended-release tablets

BUDEP XR 300 extended-release tablets

(Bupropion hydrochloride)

Read all of this leaflet carefully before you start taking BUDEP XR.

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

BUDEP XR contains bupropion hydrochloride. **BUDEP XR** has been prescribed to you for

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the treatment of depression.

The exact mechanism of action through which bupropion hydrochloride relieves depression is not fully understood, but it is believed that it interacts with chemicals called noradrenaline and dopamine in the brain.

BUDEP XR is only available with a doctor's prescription.

It may take a while before you start feeling better. It takes time for **BUDEP XR** to have its full effect, sometimes weeks or months. When you do start feeling better, your doctor may advise you to keep taking **BUDEP XR** to prevent the depression from coming back.

2. What you need to know before you take BUDEP XR

Do not take BUDEP XR:

- if you are under 18 years of age
- if you have ever had an allergic reaction to bupropion hydrochloride or any of the ingredients of **BUDEP XR**, listed in section 6. Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following: wheezing, swelling of the lips/mouth, difficulty in breathing, hay fever, lumpy rash ("hives") or fainting. Allergic reactions can last a long time. Talk to your doctor about the management of the allergic symptoms
- if you now have or ever had fits (e.g. epilepsy)
- if you are taking any other medicines which contain bupropion hydrochloride
- if you are usually a heavy drinker but you have suddenly stopped drinking alcohol or you plan to do so while taking **BUDEP XR**
- if you have suddenly stopped taking sedatives (including benzodiazepines) or you plan to do so while taking **BUDEP XR**

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- if you ever had an eating disorder (e.g. bulimia or anorexia nervosa)
- if you are taking medicines for depression called monoamine oxidase inhibitors (MAOIs) such as linezolid (used for the treatment of infections) in the last 14 days
- if you have a severe liver problem.

Warnings and precautions

Talk to your doctor or pharmacist before taking BUDEP XR:

- if you are over 65 years of age
- if you suffer from heart problems
- if you have increased blood pressure
- if you have had high pressure in the eye
- if you suffer from any mental disorder particularly mood swings (bipolar disorder also known as manic depression)
- if you suffer from kidney or liver problems (cirrhosis).
- 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.

BUDEP XR has been shown to cause fits (seizures). Fits are more likely to occur:

- if you have had a serious head injury or a history of head trauma
- if you suffer from a brain tumor
- if you have a history of fits
- if you are taking other medicines (antidepressants, antipsychotics, antimalarials, quinolone antibiotics, sedating antihistamines, theophylline, tramadol, or corticosteroids) that may increase the risk of fits
- if you regularly drink a lot of alcohol

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- if you take a lot of medication (sedatives) to treat anxiety
- if you have diabetes for which you use insulin or tablets
- if you are taking appetite suppressants.
- if you have a fit (seizure) during treatment stop taking **BUDEP XR** and don't take any more. See your doctor.

Thoughts of suicide or exacerbation of your condition:

When you are depressed you can sometimes have thoughts of harming or killing yourself. These thoughts may intensify when you first start taking antidepressants. These medicines take time to work – usually about two weeks from inception, but sometimes longer.

You may be more likely to have thoughts of harming or killing yourself if:

- you have previously had thoughts about killing or harming yourself if
- you are under 25 years old
- you feel depressed or suicidal or have recently changed your behaviour.

Some people become depressed, agitated and very occasionally, they may think about committing suicide, or try to do so. These symptoms have affected people taking bupropion, most often in the first few weeks of treatment.

If you feel depressed or think about suicide contact your doctor or go to a hospital straight away.

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

Children and adolescents

The treatment with **BUDEP XR** is not recommended for children and adolescents aged under the age of 18 years because it is unlikely to be safe.

Other medicines and BUDEP XR:

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

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist each time you get a new medicine.

Tell the doctor if you are taking:

- cyclophosphamide, ifosphamide (to treat cancer)
- prasugrel (used to prevent formation of blood clots)
- cimetidine (used to treat and prevent certain types of stomach ulcer)
- ticlopidine or clopidogrel (used to treat heart disease or stroke)
- levodopa, amantadine or orphenadrine (to treat Parkinson's disease)
- nortriptyline, desipramine, imipramine, paroxetine, fluoxetine, norfluoxetine, fluvoxamine, sertraline, citalopram, clomipramine (medicines to treat depression)
- beta blockers (such as metoprolol), mainly used to treat high blood pressure
- propafanone, flecainide to treat (irregular heart rhythm)
- haloperidol, risperidone, thioridazine, clozapine, olanzapine (to treat mental health problems)
- carbamazepine, phenobarbitone, phenytoin, lamotrigine or valproate (to treat epilepsy)
- ritonavir, lopinavir/ritonavir, nelfinavir, efavirenz (for treatment of HIV infection).

Using **BUDEP XR** and nicotine replacement therapy (i.e. nicotine patches or nicotine gum) together may raise your blood pressure. Your doctor will probably want to check your blood pressure regularly to make sure that it stays within acceptable levels.

BUDEP XR with alcohol:

Some people find they are more sensitive to alcohol while taking **BUDEP XR** Your doctor may suggest you do not drink alcohol while you're taking **BUDEP XR**, or try to drink as little as possible. If your alcohol intake is high now, do not just stop suddenly, it may put you at a risk of having a fit.

Pregnancy and breast-feeding

Do not take **BUDEP XR** XR if you are pregnant, you think you might be pregnant, planning to become pregnant, or are currently breast–feeding your baby.

If you are pregnant or breast-feeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **BUDEP XR**.

Driving and using machinery

BUDEP XR may affect your ability to drive and use machines. Make sure you know how you react to **BUDEP XR** before you drive, use machines, or engage in any other activity that could be dangerous if you are not alert.

BUDEP XR contains lactose

BUDEP XR tablets contain lactose monohydrate. If you have been told by your doctor that you have intolerance to some sugars (lactose or milk sugar), talk to your doctor before taking **BUDEP XR** tablets.

BUDEP XR contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

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3. How to take BUDEP XR

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

Always take **BUDEP XR** exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are not sure.

Take **BUDEP XR** tablets at least 24 hours apart.

BUDEP XR should be taken early in the morning with or without food.

Don't take **BUDEP XR** close to bedtime, it may cause difficulty in sleeping.

Swallow **BUDEP XR** tablets whole. Don't chew them, crush them or cut them if you do, the medicine will be released into your body too quickly. This will make you more likely to have side effects, including fits.

Dosage for depression

The usual dose is 150 mg once a day which can be increased to 300 mg once a day, if the medicine is well tolerated.

If your treatment is being changed from another bupropion medicine to **BUDEP XR**, your doctor will decide the appropriate dose.

Your doctor will periodically monitor your condition and then decide the dose and duration of treatment.

Don't stop taking **BUDEP XR** without talking to your doctor first. You may need to reduce your dose gradually.

If you have the impression that the effect of **BUDEP XR** is too weak, or too strong, talk to

your doctor or pharmacist.

If you take more BUDEP XR than you should

The symptoms of over-dose includes feeling drowsy, loss of consciousness and ECG changes. In the event of an overdosage contact your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison information centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken. You may have increased side effects and your doctor may interrupt your treatment.

If you forget to take BUDEP XR

If you forget to take a dose, do not worry. Contact your doctor as soon as possible. Take it as soon as you remember on the same day. If you do not take the tablet on the same day, take your normal dose on the next day. Do not take a double dose to make up for forgotten individual doses.

If you stop taking BUDEP XR

You must take **BUDEP XR** every day. **BUDEP XR** helps to control your condition, but it is not a cure for it. It is important not to stop taking **BUDEP XR** XR just because you feel better as your condition may then deteriorate.

If you have any further questions on the use of **BUDEP XR**, ask your doctor or pharmacist.

4. Possible side effects

BUDEP XR can have side effects.

Not all side effects reported for **BUDEP XR** are included in this leaflet. Should your general

health get worse or if you experience any untoward effects while taking this medication, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens stop taking **BUDEP XR** and tell your doctor immediately or go to the casualty department of your nearest hospital:

Less frequent side effects:

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing, low blood pressure, fever, pain (anaphylactic reaction, delayed hypersensitivity)
- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson Syndrome)
- red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body. The spots may blister or may progress to form raised, red, pale-centered marks. Those affected may have fever, sore throat, headache and/or diarrhoea (erythema multiforme)
- severe flaking or peeling of the skin (exfoliative dermatitis)
- seizures (fits): Some patients taking the maximum dose of **BUDEP XR** is at risk of a seizure. The chance of this happening is higher if you take too high a dose, if you take certain medicines in combination with **BUDEP XR**, or if you are at a higher than usual risk for of seizures (fits) than the population at large. If you are worried, talk to your doctor. If you have a fit, tell your doctor when you have recovered. Do not take any more tablets.

These are all very serious side effects. If they occur, you may have had a serious reaction to **BUDEP XR**. You may need urgent medical attention or hospitalisation.

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Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following. In some cases your doctor may need to reduce your dose of **BUDEP XR** or interrupt treatment:

Less frequent side effects:

- yellowing of the skin or eyes, abdominal pain, unexplained fatigue, dark coloured urine or pale coloured stools; these may be manifestations of a liver problem (jaundice, hepatitis), liver damage
- fits, stroke
- severe abdominal pain with feeling sick (nausea) or being sick (vomiting). These may be manifestations of pancreatitis
- Severe changes in mental condition, including aggression, rage and violent behaviour (psychosis or mania).

Frequency unknown:

- thoughts about suicide and self-harm (suicidal ideation), suicidal behaviour or tendency, actual suicide. Suicide has been reported with bupropion use.

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:

- headache or migraine, dizziness, sleepiness, feeling nervous
- itching, sweating, skin rash, hives
- shakiness, tremor
- feeling anxious or agitated, unable to sleep
- dry mouth, stomach pain or other upsets (feeling sick, vomiting, constipation), loss of appetite, weight gain or weight loss (more than 2,5 kg)
- changes in blood pressure, flushing

- ringing in ears, hearing problem, visual disturbances, loss of taste
- sore throat and discomfort when swallowing (pharyngitis)
- feeling of tension or fullness in the nose, cheeks and behind your eyes (sinusitis), cough
- weakness, tiredness, fever, chest pain
- menstrual complaints
- restlessness or difficulty sitting still (akathisia)
- decreased sexual drive.

Less frequent side effects:

- changes in blood sugar levels
- feeling confused, feeling depressed
- 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 (paraesthesia), loss of memory
- difficulty concentrating
- uncontrolled movements, twitching, muscle stiffness, problems with walking or coordination
- fainting (syncope)
- raised heart rate (fast, slow or irregular)
- palpitations, hot flashes, increased or decreased blood pressure
- dizziness on standing up, especially when getting up from a sitting or lying position (postural hypotension)
- widening of blood vessels (vasodilation)
- raised liver enzymes

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- severe allergic reactions; rash together with joint and muscle pains
- urinating more or less than usual, urgent need to urinate, difficulty or pain when passing urine. These might be a symptoms of urinary tract infection
- abnormal vaginal bleeding (vaginal haemorrhage).

Frequency unknown:

- bruising (ecchymosis)
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale. These are all symptoms of a condition known as anaemia or pancytopenia
- increase or decrease in white blood cells (leucocytosis, leukopenia)
- swollen glands in the neck, armpit or groin (lymphadenopathy)
- bleeding or bruising more easily than normal (thrombocytopenia)
- bleeding or blood clotting complications
- sugar (glucose) in the urine (glycosuria)
- abnormal coordination
- feeling disconnected or detached from one's body and thoughts (depersonalization)
- emotional lability
- unusually overactive (hyperkinesia)
- unusual muscle stiffness causing poor control of movement (hypertonia)
- excessive physical sensitivity, especially of the skin (hyperesthesia)
- spinning sensation (vertigo)
- loss of memory (amnesia)
- a feeling that one's surroundings are not real, especially as a symptom of mental disturbance (derealisation)
- abnormal record of the electrical activity of the brain

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- lack of normal movement (akinesia)
- inability to comprehend or formulate language (aphasia)
- coma
- difficulty in speaking (dysarthria)
- uncontrollable twitching, jerking or writhing movements (dyskinesia, unmasking tardive dyskinesia)
- feeling of extreme happiness (euphoria)
- uncontrollable movements (extrapyramidal syndrome)
- unusually reduced or slow body movement (hypokinesia)
- increased sexual drive
- severe stabbing or throbbing pain along one or more nerves (neuralgia)
- numbness or weakness of the arms and legs (neuropathy)
- dry eye
- increased pressure in the eye (angle-closure glaucoma)
- dilated pupils (mydriasis)
- collapse, numbness or weakness of the arms or legs, headache, dizziness and confusion, visual disturbance, difficulty swallowing, slurred speech and loss of speech. These could be symptoms of stroke
- unusual fast heart beat (extrasystoles)
- swelling and redness along a vein which is extremely tender when touched (phlebitis)
- blockage of lung artery (pulmonary embolism)
- serious lung infection (pneumonia)
- grind, gnash or clench your teeth (bruxism)
- heartburn
- inflammation of the gums (gingivitis)

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- swollen, red, sore tongue (glossitis)
- increased salivation
- mouth ulcers (stomatitis)
- thirst
- diarrhoea, usually with blood and mucus, stomach pain, fever (colitis)
- inflammation of the food pipe (esophagitis)
- bleeding in the gastrointestinal tract, from the mouth to the rectum
- ruptured bowel (intestinal perforation)
- high sugar (glucose) levels in the blood. The symptoms may include passing large amounts of urine, excessive thirst and having a dry mouth and skin (hyperglycaemia)
- low sugar (glucose) levels in the blood (hypoglycaemia)
- excessive hairiness, particularly in women (hirsutism)
- leg cramps
- temporary paralysis or weakness of muscles (rhabdomyolysis)
- inability to get or maintain an erection (impotence)
- passing more urine than normal (polyuria)
- abnormal ejaculation
- inflammation of the bladder (cystitis)
- painful sexual intercourse (dyspareunia)
- pain when passing urine (dysuria)
- breast enlargement in men (gynecomastia)
- menopause
- painful erection
- inflammation of the fallopian tubes (salpingitis)
- uncontrollable, involuntary passing of urine (urinary incontinence)[j]

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- discharge and itching in the vagina due to infection (vaginitis)
- increased sensitivity of the skin to sun (photosensitivity).

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 increase when first starting antidepressants. These medicines can take time to work – usually about two weeks, but sometimes longer (see **Take special care with BUDEP XR).**

Children under 18 years of age:

BUDEP XR should not be used to treat children under 18 years of age. There is an increased risk of suicidal thoughts and behavioural problems when children under 18 years of age are treated with antidepressants.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **BUDEP XR**.

Suspected adverse reactions can also be reported directly to the Holder of Certificate of Registration (HCR) via email: pharmacovigilance.africasme@sunpharma.com or tel: +27(0)

12 643 2000.

5. How to store BUDEP XR

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Keep in the original package until required for use.
- Return all unused medicines to your pharmacist.
- Do not dispose of unused medicines in drains or sewerage systems.

6. Contents of the pack and other information

What BUDEP XR contains

The active substance is bupropion hydrochloride.

BUDEP XR 150: Each extended release tablet contains 150 mg bupropion hydrochloride.

Contains sugar: lactose monohydrate 4,76 mg per tablet.

BUDEP XR 300: Each extended release tablet contains 300 mg bupropion hydrochloride.

Contains sugar: lactose monohydrate 9,73 mg per tablet.

The other ingredients are: Ethyl cellulose (ethocel 45 cps standard premium), glycerylbehenate (Compritol ATO 888), hydroxypropyl cellulose (HPC-L), hypromellose (Methocel E5 premium), isopropyl alcohol, methacrylic acid copolymer dispersion (Eudragit L30D-55), methylene chloride, Opacode S-1-17823 (black), polyethylene glycol 6000, povidone (plasdone K90 D), purified water, silicon dioxide (Syloid 244 FP), stearic acid and triethyl citrate.

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What BUDEP XR looks like and contents of the pack

BUDEP XR 150: White to cream, round, film-coated tablets imprinted with "**L2**" in black ink on one side and plain on the other side.

BUDEP XR 300: White to pale yellow, round, film-coated tablets imprinted with "**L**" in black ink on one side and plain on the other side.

BUDEP XR 150 and **BUDEP XR 300** tablets are packed in HDPE bottles. Each HDPE bottle contains 30 tablets.

HDPE Bottle pack:

White opaque HDPE bottle with white opaque screw closure with induction seal liner and an HDPE 1 g desiccant canister containing activated silica gel (60 %) and activated carbon (40 %).

Holder of Certificate of Registration

RANBAXY PHARMACEUTICALS (PTY) LTD

14 Lautre Road, Stormill, Ext.1,

Roodepoort, 1724

South Africa

Telephone: +27(0) 12 643 2000

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Registration numbers

BUDEP XR 150: 48/1.2/0114

BUDEP XR 300: 48/1.2/0115

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Access to the corresponding PIL translation:

The PIL is available in one other language (Afrikaans), a copy is accessible on the company website: https://sunpharma.com/south-africa-products/

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