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
2. What you need to know before you take **BUDEP XR**
3. How to take **BUDEP XR**
4. Possible side effects
5. How to store **BUDEP XR**
6. Contents of the pack and other information

1. What BUDEP XR is and what it is used for

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

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**

- 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

- 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.

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.

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

- 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

- 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)

- 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]

- 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.

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

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BUDEP XR 150: 48/1.2/0114

BUDEP XR 300: 48/1.2/0115

Access to the corresponding professional information

SKEDULERINGSTATUS:

S5

BUDEP XR 150 Verlengde-vrystelling Tablette

BUDEP XR 300 Verlengde-vrystelling Tablette

(Bupropion hidrochloried)

Lees die hele pamflet aandagtig deur voordat u BUDEP XR inneem.

- Bewaar hierdie pamflet. U moet dit miskien weer lees.
- Vra u dokter of apteker as u enige verdere vrae het.
- **BUDEP XR** is persoonlik aan u voorgeskryf en u moet u medisyne nie met ander mense deel nie. Dit kan hulle benadeel, selfs al is hulle simptome dieselfde as u s'n.

Wat is in hierdie pamflet

1. Wat **BUDEP XR** is en waarvoor dit gebruik word

2. Wat u moet weet voordat u **BUDEP XR** neem

3. Hoe om **BUDEP XR** te neem

4. Moontlike newe-effekte

5. Hoe om **BUDEP XR** te stoor

6. Inhoud van die verpakking en ander inligting.

1. WAT BUDEP XR IS EN WAARVOOR DIT GEBRUIK WORD

BUDEP XR bevat bupropionhidrochloried. **BUDEP XR** is aan u voorgeskryf vir die behandeling van depressie.

Die presiese werkingsmeganisme waardeur bupropionhidrochloried depressie verlig, word nie ten volle verstaan nie, maar daar word geglo dat dit in wisselwerking is met chemikalieë wat noradrenalien en dopamien in die brein genoem word.

BUDEP XR is slegs op doktersvoorskrif beskikbaar.

Dit kan 'n rukkie duur voordat u beter begin voel. Dit neem tyd voordat **BUDEP XR** sy volle effek het, soms weke of maande. As u wel beter begin voel, kan u dokter u aanraai om met die behandeling aan te hou om te verhoed dat die depressie terugkom.

2. WAT U MOET WEET VOORDAT U BUDEP XR NEEM

Moenie BUDEP XR neem nie:

- as u jonger as 18 is
- as u ooit 'n allergiese reaksie vir bupropionhidrochloried of enige van die bestanddele van **BUDEP XR** gehad het, soos in afdeling 6 gelys. Simptome van 'n allergiese reaksie kan lig of ernstig wees. Dit bevat gewoonlik 'n paar of al die volgende simptome: kortasem, swelling van die lippe / mond, asemhalingsprobleme, hooikoors, knopagtige uitslag ("korwe") of floute. Allergiese reaksies kan lank duur. Praat met u dokter oor die hantering van allergiese simptome.
- as u nou aanvalle het of ooit gehad het (bv. epilepsie)
- as u ander medisyne gebruik wat bupropionhidrochloried bevat
- as u gewoonlik 'n strawwe drinker is, maar het skielik opgehou drink, of as u van plan is om dit te doen terwyl u **BUDEP XR** inneem
- as u skielik opgehou het met die gebruik van kalmeermiddels (insluitend bensodiasepiene) of as u van plan is om dit te doen terwyl u **BUDEP XR** neem
- as u ooit eetstoornis gehad het (bv. bulimie of anorexia nervosa)
- as u die afgelope 14 dae medisyne vir depressie geneem het wat monoamienoksidaseremmers (MAO-remmers) genoem word, soos linesolied (wat gebruik word vir die behandeling van infeksies).
- as u 'n ernstige lewerprobleem het.

Waarskuwings en voorsorgmaatreëls

Praat met jou dokter of apteker voordat jy BUDEP XR neem:

- as u ouer as 65 is
- as u aan hartprobleme ly
- as u verhoogde bloeddruk het
- as u hoë druk in die oog gehad het
- as u aan 'n geestesversteuring ly, veral buierigheid (bipolêre versteuring, ook bekend as maniese depressie)
- as u nier- of lewerprobleme (sirrose) het.
- Hartgeleidingsversteurings bv. Brugada-sindroom - as jy 'n toestand genaamd Brugada-sindroom het ('n seldsame oorerflike sindroom wat die hartritme aantas) of as hartstilstand of skielike dood in jou gesin voorgekom het.

BUDEP XR het getoon dat dit aanvalle (epilepsie) veroorsaak. Dit is meer waarskynlik dat aanvalle sal voorkom:

- as u 'n ernstige kopbesering of 'n geskiedenis van koptrauma gehad het
- as u aan 'n breingewas ly
- as u 'n geskiedenis van aanvalle het
- as u ander medisyne gebruik (antidepressante, antipsigotika, malariamiddels, kinoloonantibiotika, kalmerende antihistamiene, teofillien, tramadol of kortikosteroïede) wat die risiko van aanvalle kan verhoog
- as u gereeld baie alkohol drink
- as u baie medisyne (kalmeermiddels) gebruik om angs te behandel
- as u suikersiekte het waarvoor u insulien of tablette gebruik
- as u eetlusdempers gebruik.
- as u 'n aanval (aanval) tydens die behandeling het, stop dan met die gebruik van **BUDEP XR** en neem nie meer nie. Gaan na u dokter.

Gedagtes oor selfmoord of verergering van u toestand:

As u depressief is, kan u soms dink dat u uself skade berokken of doodmaak. Hierdie gedagtes kan vererger wanneer u die eerste keer antidepressante begin gebruik. Dit neem tyd om te werk - gewoonlik ongeveer twee weke vanaf die begin, maar soms langer.

U kan meer geneig wees om jouself te benadeel of te vermoor as:

- u al voorheen gedagtes gehad het om uself dood te maak of te benadeel
- u jonger as 25 is
- u depressief is of voel om selfmoord te pleeg of u gedrag onlangs verander het.

Sommige mense raak depressief, prikkelbaar en soms kan hulle daaraan dink om selfmoord te pleeg, of probeer om dit te doen. Hierdie simptome het mense wat bupropion inneem, beïnvloed, meestal in die eerste paar weke van behandeling.

As u depressief voel of aan selfmoord dink, kontak u dokter of gaan dadelik na 'n hospitaal.

As een van die bogenoemde op u van toepassing is, sal u dokter daaraan aandag skenk of 'n ander behandeling aanbeveel.

Kinders en tieners

Die behandeling met **BUDEP XR** word nie aanbeveel vir kinders en tieners onder die ouderdom van 18 jaar nie, omdat dit waarskynlik nie veilig is nie.

Ander medisyne en BUDEP XR:

Vertel altyd vir u gesondheidswerker as u ander medisyne gebruik (dit sluit aanvullende of tradisionele medisyne in).

Ken die medisyne wat u neem. Hou 'n lys daarvan om u gesondheidsorgverskaffer en apteker te wys elke keer as u 'n nuwe medisyne kry.

Vertel die dokter as u die volgende gebruik:

- siklofosfamied, ifosfamied (vir die behandeling van kanker)
- prasugrel (gebruik om bloedklontvorming te voorkom)

- simetidien (word gebruik om sekere soorte maagsweer te behandel en te voorkom)
- tiklopidien of klopidogrel (word gebruik om hartsiektes of beroerte te behandel)
- levodopa, amantadien of orfenadrien (vir die behandeling van Parkinson se siekte)
- nortriptilien, desipramie, imipramie, paroksetien, fluoksetien, norfluoksetien, fluvoksamien, sertralie, sitalopram, klomipramien (medisyne om depressie te behandel)
- beta-blokkers (soos metoprolol), wat hoofsaaklik gebruik word om hoë bloeddruk te behandel
- propafanoon, flekainied (om onreëlmatige hartritme te behandel)
- haloperidol, risperidon, tioridasien, closapien, olansapien (vir die behandeling van geestesgesondheidsprobleme)
- karbamasepien, fenobarbitoon, fenitoïn, lamotrigien of valproaat (vir die behandeling van epilepsie)
- ritonavir, lopinavir / ritonavir, nelfinavir, efavirenz (vir die behandeling van MIV-infeksie).

As u **BUDEP XR** en nikotienvervangingsterapie (dws nikotienplakkers of nikotiengom) saam gebruik, kan u bloeddruk verhoog. U dokter sal waarskynlik u bloeddruk gereeld wil nagaan om seker te maak dat dit binne aanvaarbare vlakke bly.

BUDEP XR met alkohol:

Sommige mense vind dat hulle meer sensitief is vir alkohol as hulle **BUDEP XR** neem. U dokter kan voorstel dat u nie alkohol drink terwyl u **BUDEP XR** gebruik nie, of probeer om so min as moontlik te drink. As u alkoholinname nou hoog is, moet u nie net skielik stop nie, u kan die risiko loop om ‘n aanval te kry.

Swangerskap en borsvoeding

Moenie **BUDEP XR** neem as u swanger is nie, dink dat u swanger is, van plan is om swanger te word of u baba tans borsvoed.

As u swanger is of u baba borsvoed, raadpleeg u dokter, apteker of ander gesondheidswerker vir advies voordat u **BUDEP XR** neem.

Bestuur en gebruik van masjinerie

BUDEP XR kan u vermoë om te bestuur en masjiene te gebruik beïnvloed. Sorg dat u weet hoe u op **BUDEP XR** reageer voordat u bestuur, masjiene gebruik of enige ander aktiwiteit doen wat gevaarlik kan wees as u nie waaksaam is nie.

BUDEP XR bevat laktose

BUDEP XR-tablette bevat laktosemonohidraat. As u dokter u meegedeel het dat u sommige suikers (laktose of melksuiker) nie verdra nie, moet u met u dokter praat voordat u **BUDEP XR**-tablette inneem.

BUDEP XR bevat laktose wat 'n effek kan hê op die beheer van u bloedsuiker as u diabetes mellitus het.

3. HOE OM BUDEP XR TE NEEM

Moenie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie.

Neem **BUDEP XR** altyd presies soos u dokter u opdrag gegee het. Raadpleeg u dokter of apteker as u nie seker is nie.

Neem **BUDEP XR**-tablette minstens 24 uur uitmekaar.

BUDEP XR kan vroegoggend met of sonder kos geneem word.

Moenie **BUDEP XR** naby slaaptyd neem nie, dit kan probleme veroorsaak om te slaap.

Sluk **BUDEP XR**-tablette heel in. Moet dit nie kou, fyndruk of sny as u dit doen nie, die medisyne sal te vinnig in u liggaam vrygestel word. Dan sal u meer geneig wees om newe-effekte te hê, insluitend aanvalle.

Dosis vir depressie

Die gewone dosis is 150 mg een keer per dag, wat verhoog kan word tot 300 mg een keer per dag, indien die medisyne goed verdra word.

As u behandeling van 'n ander bupropion medisyne na **BUDEP XR** verander, sal u dokter op die toepaslike dosis besluit.

U dokter sal u toestand gereeld monitor en dan die dosis en duur van die behandeling bepaal.

Moenie ophou om **BUDEP XR** te neem sonder om eers met u dokter te praat nie. U moet u dosis geleidelik verminder.

As u die indruk het dat die effek van **BUDEP XR** te swak of te sterk is, moet u met u dokter of apteker praat.

As u meer BUDEP XR geneem het as wat u moes

Die simptome van 'n oordosis sluit in dat u slaperig raak, dat u bewusteloosheid en EKG verander. In geval van oordosering, kontak u dokter of apteker onmiddellik.

Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifinligtingsentrum. Neem hierdie pamflet en die oorblywende tablette saam, sodat die dokter weet wat u geneem het. U kan newe-effekte hê, en u dokter kan u behandeling onderbreek.

As u vergeet het om BUDEP XR te neem

Moenie bekommerd wees as u vergeet het om 'n dosis te neem nie. Kontak u dokter so spoedig moontlik.

Neem dit sodra u op dieselfde dag onthou. As u die tablet nie dieselfde dag inneem nie, neem dan die volgende dag u normale dosis. Moenie 'n dubbele dosis neem om die vergete dosisse

As u opgehou het om BUDEP XR te neem

U moet elke dag **BUDEP XR** neem, dit help om u toestand te beheer, maar dit is nie 'n genesing daarvoor nie. Dit is belangrik om nie op te hou om **BUDEP XR** te neem net omdat u beter voel nie omdat u toestand dan kan verswak.
Vra u dokter of apteker as u verdere vrae het oor die gebruik van **BUDEP XR**.

4. MOONTLIKE NEWE-EFFEKTE

BUDEP XR kan newe-effekte hê. Nie alle newe-effekte wat vir **BUDEP XR** gerapporteer is nie, is in hierdie pamflet ingesluit nie. Raadpleeg u dokter, apteker of ander gesondheidswerker vir advies indien u algemene gesondheid erger word of as u enige ongewenste effekte ervaar.
As u een van die volgende newe-effekte ervaar, staak die inname van **BUDEP XR** en vertel dit onmiddellik aan u dokter of gaan na die ongevalle-afdeling van u naaste hospitaal:
Minder gereelde newe-effekte:

- skielike tekens van allergie soos uitslag, jeuk of korwe op die vel, swelling in die gesig, lippe, tong of ander liggaamsdele, kortasem, hygende asemhaling of probleme met asemhaling, lae bloeddruk, koors, pyn (anafilaktiese reaksie vertraagde hipersensitiwiteit)
- 'n wydverspreide uitslag met blase en afskilferende vel, veral rondom die mond, neus, oë en geslagsdele (Stevens-Johnson-sindroom)
- rooi, dikwels jeukende kolle, soortgelyk aan die uitslag van masels, wat op die ledemate en soms op die gesig en die res van die liggaam begin. Die kolle kan blase vorm of vorder tot verhoogde, rooi, liggeel merke. Diegene wat geraak word, kan koors, keelseer, hoofpyn en / of diarree hê (erythema multiforme)
- ernstige vormingvan vlokke of afskilfering van die vel (eksfoliatiewe dermatitis)
- aanvalle: Sommige pasiënte wat die maksimum dosis **BUDEP XR** inneem, loop die risiko van 'n aanval. Die kans dat dit sal gebeur, is groter as u 'n te hoë dosis inneem, as u sekere medisyne in kombinasie met **BUDEP XR** inneem, of as u 'n groter kans het as

gewoonlik vir aanvalle as die bevolking in die algemeen . As u bekommerd is, praat met u dokter. As u ‘n aanval gehad het, vertel dit aan u dokter wanneer u herstel het. Neem nie meer tablette nie.

Dit is alles baie ernstige newe-effekte. As dit voorgekom het, het u moontlik 'n ernstige reaksie op **BUDEP XR** gehad. U benodig moontlik dringende mediese hulp of hospitalisasie.

Vertel dit dadelik aan u dokter of gaan na die ongevalle-afdeling in u naaste hospitaal as u een van die volgende opmerk. In sommige gevalle sal u dokter u dosis **BUDEP XR** moet verminder of die behandeling moet onderbreek:

Minder gereelde newe-effekte:

- vergeling van die vel of oë, buikpyn, onverklaarbare moegheid, donkerkleurige urine of ligkleurige ontlasting; dit kan manifestasies wees van 'n lewerprobleem (geelsug, hepatitis), lewerskade
- aanvalle, beroerte
- erge buikpyn met naarheid of braking. Dit kan manifestasies van pankreatitis wees
- ernstige veranderinge in geestestoestande, insluitend aggressie, woede en gewelddadige gedrag (psigose of manie).

Frekwensie onbekend:

- gedagtes oor selfmoord en selfskending (selfmoordgedagtes), selfmoordgedrag of neiging, werklike selfmoord. Selfmoord is aangemeld met die gebruik van bupropion.

Dit is alles ernstige newe-effekte. U benodig moontlik dringende mediese hulp.

Vertel u dokter as u een van die volgende opmerk:

Gereelde newe-effekte:

- hoofpyn of migraine, duiseligheid, slaperigheid, senuweeagtigheid
- jeuk, sweet, veluitslag, korwe
- bewerigheid, bewing

- angstig of opgewonde voel, nie in staat is om te slaap nie
- droë mond, maagpyn of ander ontsteltenis (braking, hardlywigheid), eetlus, gewigstoename of gewigsverlies (meer as 2,5 kg)
- veranderinge in bloeddruk, bloos
- ringgeluid in die ore, gehoorprobleme, gesigstoornisse, smaakverlies
- keelpyn en ongemak tydens sluk (keelontsteking)
- gevoel van spanning of volheid in die neus, wange en agter u oë (sinusitis), hoes
- swakheid, moegheid, koors, borspyn
- menstruele klagtes
- rusteloosheid of probleme om stil te sit (akathisia)
- verminderde seksuele dryfkrag.

Minder gereelde newe-effekte:

- veranderinge in bloedsuikervlakke
- verward voel, depressief voel
- voel onrustig, geïrriteerd, vyandig, aggressief of paranoïes, voel onwerklik of vreemd (depersonalisering), voel of dinge glo wat nie daar is nie (hallusinasies / dwalings), vreemde drome, tinteling of gevoelloosheid (parestesie), geheueverlies
- sukkel om te konsentreer
- ongekontroleerde bewegings, rukkings, spierstyfheid, probleme met loop of koördinasie
- floute (sinkopee)
- verhoogde hartklop (vinnig, stadig of onreëlmatig)
- hartkloppings, warm gloede, verhoogde of verlaagde bloeddruk
- duiseligheid tydens opstaan, veral as u uit 'n sit- of lêposisie opstaan (posturale hipotensie)
- verwyding van bloedvate (vasodilatasie)
- verhoogde lewerensieme

- ernstige allergiese reaksies; uitslag tesame met gewrigs- en spierpyn
- urinering min of meer as gewoonlik, dringende behoefte om te urineer, probleme of pyn as u urineer. Dit kan simptome van urienweginfeksie wees
- abnormale vaginale bloeding (vaginale bloeding).

Frekwensie onbekend:

- kneusplekke (ekkimose)
- moegheid, hoofpyn, kortasem tydens oefening, duiseligheid en bleek lyk. Dit is alles simptome van 'n toestand wat bekend staan as bloedarmoede of pankitopenie
- toename of afname in witbloedselle (leukositose, leukopenie)
- geswelde kliere in die nek, oksel of lies (limfadenopatie)
- bloeding of kneusplekke makliker as normaal (trombositopenie)
- bloeding of bloedstollingskomplikasies
- suiker (glukose) in die urine (glikosurie)
- abnormale koördinasie
- ontkoppel of los van die liggaam en gedagtes (depersonalisering)
- emosionele labiliteit
- buitengewoon ooraktief (hiperkinesie)
- ongewone spierstyfheid wat swak beheer van beweging veroorsaak (hipertonie)
- oormatige fisiese sensitiwiteit, veral van die vel (hiperestesie)
- spin sensasie (vertigo)
- geheueverlies (geheueverlies)
- 'n gevoel dat 'n mens se omgewing nie werklik is nie, veral as 'n simptoom van geestelike versteuring (derealisering)
- abnormale rekord van die elektriese aktiwiteit van die brein
- gebrek aan normale beweging (akinesie)
- onvermoë om taal te verstaan of te formuleer (afasie)

- koma
- probleme met praat (dysartrie)
- onbeheerbare ruk-, ruk- of kriewelbewegings (dyskinesie, ontmaskerende tardiewe dyskinesie)
- gevoel van uiterste geluk (euforie)
- onbeheerbare bewegings (ekstrapiramidale sindroom)
- ongewone verminderde of stadige liggaamsbeweging (hipokinesie)
- verhoogde seksuele dryfkrag
- erge steek- of kloppende pyn langs een of meer senuwees (neuralgie)
- gevoelloosheid of swakheid van die arms en bene (neuropatie)
- droë oog
- verhoogde druk in die oog (gloukoom met hoeksluiting)
- verwydde pupille (mydriasis)
- ineenstorting, gevoelloosheid of swakheid van die arms of bene, hoofpyn, duiseligheid en verwarring, gesigversteuring, sukkel om te sluk, sluwe spraak en spraakverlies. Dit kan simptome van beroerte wees
- ongewone vinnige hartklop (ekstrasistoles)
- swelling en rooiheid langs 'n aar wat baie sag is as dit aangeraak word (flebitis)
- verstopping van longslagaar (longembolie)
- ernstige longinfeksie (longontsteking)
- maal, kners of tande kners (bruxisme)
- sooibrand
- tandvleisontsteking (tandvleisontsteking)
- geswelde, rooi, seer tong (glossitis)
- verhoogde speekselafskeiding
- mondsere (stomatitis)

- dors
- diarree, gewoonlik met bloed en slym, maagpyn, koors (kolitis)
- ontsteking van die voedselpyp (slukderm)
- bloeding in die spysverteringskanaal, van die mond tot die rektum
- gebreekte derm (dermperforasie)
- hoë suiker (glukose) vlakke in die bloed. Die simptome kan insluit die uitskeiding van groot hoeveelhede urine, oormatige dors en 'n droë mond en vel (hiperglukemie)
- lae suiker (glukose) vlakke in die bloed (hipoglisemie)
- oormatige harigheid, veral by vroue (hirsutisme)
- beenkrampe
- tydelike verlamming of swakheid van spiere (rabdomiolise)
- onvermoë om 'n ereksie te kry of te onderhou (impotensie)
- meer urinering as normaalweg (poliurie)
- abnormale ejakulasie
- ontsteking van die blaas (sistitis)
- pynlike geslagsgemeenskap (dyspareunia)
- pyn tydens urinering (disurie)
- borsvergroting by mans (ginekomastie)
- menopouse
- pynlike ereksie
- ontsteking van die fallopiese buise (salpingitis)
- onbeheerbare, onwillekeurige urinering (urinêre inkontinensie))
- ontslag en jeuk in die vagina as gevolg van infeksie (vaginitis)
- verhoogde sensitiwiteit van die vel vir son (fotosensitiwiteit).

Gedagtes van selfmoord of verergering van u toestand

As u depressief is, kan u soms dink om uself te benadeel of te vermoor. Hierdie gedagtes kan toeneem as u eers met antidepressante begin. Hierdie medisyne neem tyd om te werk - gewoonlik ongeveer twee weke, maar soms langer (sien **Wees veral versigtig met BUDEP XR**).

Kinders jonger as 18 jaar:

BUDEP XR moet nie gebruik word vir die behandeling van kinders jonger as 18 jaar nie. Daar is 'n verhoogde risiko vir selfmoordgedagtes en gedragsprobleme wanneer kinders jonger as 18 jaar met antidepressante behandel word.

As u enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, moet u u dokter of apteker daarvan in kennis stel.

Rapportering van newe-effekte

Indien jy newe-effekte kry, bespreek dit met joy dokter, apteker of verpleegster.

Jy kan ook newe-effekte aanmeld aan SAHPRA via die Med Safety APP (Medsafety X SAHPRA) en die e-verslagverskaffing platform (who-umc.org) wat op SAHPRA se webwerf gevind kan word. Deur newe-effekte aan te meld, kan u help om meer inligting aangaande die die veiligheid van **BUDEP XR** te verskaf.

As nadelige reaksies vermoed word kan die ook aan die Houer van sertifikaat van registrasie per e-pos of telefonies gerapporteer word: pharmacovigilance.africasme@sunpharma.com of tel: +27(0) 12 643 2000.

5. HOE OM BUDEP XR TE BERG

Stoor alle medisyne buite bereik van kinders.

- Bewaar by of benede 25 ° C.
- Bewaar in die oorspronklike verpakking totdat dit benodig word.

- Stuur alle ongebruikte medisyne aan u apteker.
- Moenie ongebruikte medisyne weggooi in riool of rioolstelsels nie.

6. INHOUD VAN DIE VERPAKKING EN ANDER INLIGTING

Wat BUDEP XR bevat

Die aktiewe bestanddeel is bupropionhidrochloried.

BUDEP XR 150: Elke tablet met verlengde vrystelling bevat 150 mg bupropionhidrochloried.

Bevat suiker: laktosemonohidraat 4,76 mg per tablet.

BUDEP XR 300: Elke tablet met verlengde vrystelling bevat 300 mg bupropionhidrochloried.

Bevat suiker: laktosemonohidraat 9,73 mg per tablet.

Die ander bestanddele is: etiel sellulose (ethocel 45 cps standard premium), gliserielbehenaat (Compritol ATO 888), hidroksiepropielsellulose (HPC-L), hipromellose (Methocel E5 premium), isopropielalkohol, metakrilsuur kopolimeer dispersie (Eudragit L30D-55) , metileenchloried, Opacode S-1-17823 (swart), poliëtileenglikool 6000, povidoon (plasdoon K90 D), gesuiwerde water, silikondioksied (Syloid 244 FP),steariensuur en trietielsitraat.

Hoe BUDEP XR lyk en die inhoud van die verpakking

BUDEP XR 150: Wit tot room, ronde, filmomhulde tablette bedruk met “**L2**” in swart ink aan die een kant en glad aan die ander kant.

BUDEP XR 300: Wit tot liggeel, ronde, filmomhulde tablette bedruk met “**L**” in swart ink aan die een kant en glad aan die ander kant.

BUDEP XR 150 en **BUDEP XR 300** tablette word verpak in HDPE-bottels. Elke HDPE bottel bevat 30 tablette.

HDPE Bottelverpakking:

Wit ondeursigtige HDPE-bottel met wit ondeursigtige skroefsluiting met induksie-seëlvoering en 'n HDPE 1 g-droogmiddelhouer wat geaktiveerde silikagel (60%) en geaktiveerde koolstof (40%) bevat.

Houer vand die registrasiesertifikaat

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Registrasienommers

BUDEP XR 150: 48/1.2/0114

BUDEP XR 300: 48/1.2/0115