Patient Information Leaflet

SCHEDULING STATUS: S5

VOXRA XL 150 mg extended-release tablets

VOXRA XL 300 mg extended-release tablets

Bupropion hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking VOXRA XL.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist, nurse or other healthcare provider
- VOXRA 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.
- If you get any side effects, talk to your doctor or pharmacist, nurse or other healthcare provider. This includes any possible side effects not listed in this leaflet (see section 4).

What is in this leaflet:

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

1. What VOXRA XL is and what it is used for:

VOXRA XL is a medicine prescribed by your doctor to treat your depression. It's thought to interact with chemicals in the brain called noradrenaline and dopamine, which are linked with depression.

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

Your doctor has chosen this medicine to suit you and your condition. Don't pass it on to others. Before deciding on treatment with VOXRA XL, you and your doctor will probably have discussed the risks of harm and the benefits that it is likely to have for you. This leaflet will help you to take VOXRA XL safely.

2. What you need to know before you take VOXRA XL:

Do not take VOXRA XL:

- if you know that you are allergic to VOXRA XL, bupropion, or any of the other ingredients in VOXRA XL tablets (listed in section 6)
- if you are taking any other medicines which contain bupropion
- if you have been diagnosed with epilepsy or have a history of seizures (fits)
- if you have brain tumour
- if you have or have had an eating disorder (e.g., bulimia or anorexia nervosa)
- if you are usually a heavy drinker who has just stopped or are about to stop drinking
- if you recently stopped taking tranquillisers or sedatives, or if you are going to stop them while you're taking VOXRA XL
- if you have been taking other medicines for depression called monoamine oxidase inhibitors (MAOIs) in the last 14 days

- If you have severe liver problems
- if you are less than 18 years of age. There is an increased risk of suicidal thoughts and behaviour when children under 18 years of age are treated with antidepressants.

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

- If you are a woman of child-bearing potential and not using contraception.

Warnings and precautions:

Talk to your doctor or pharmacist or healthcare provider before taking VOXRA XL:

- if you've ever had any fits or seizures in the past
- if you have a brain tumour
- if you have liver or kidney problems
- if you regularly drink a lot of alcohol
- if you have diabetes for which you use insulin or tablets
- if you have had any mental illness other than depression
- if you have had a serious head injury
- if you are over 65 years of age
- if you are pregnant or plan to become pregnant soon
- if you suffer from high blood pressure
- Cardiac conduction disorders (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.

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

Thoughts of suicide or worsening of your condition:

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

You may be more likely to think like this:

- if you have previously had thoughts about killing or harming yourself
- if you are under 25 years old.
- if you feel your depression getting worse.

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).

Other medicines with VOXRA XL:

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

If you have been taking other medicines for depression called monoamine oxidase inhibitors (MAOIs) in the last 14 days, tell your doctor before taking VOXRA XL.

If you are taking any other medicines, herbs or vitamins, including products you bought yourself, tell your doctor. He or she may alter your dose of VOXRA XL or suggest a change in your other medications.

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

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

- if you take medicines which make seizures (fits) more likely e.g., theophylline for asthma or lung disease, or tramadol (a strong painkiller)
- if you have been taking tranquillisers or sedatives, or if you are going to stop them while you're taking VOXRA XL

- if you take stimulants or other medicines to control your weight or appetite
- if you take medicines against malaria (such as mefloquine or chloroquine)
- If you take antibiotics called quinolones.

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

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

- if you take certain other medicines for depression or other mental illness (such as desipramine or selective serotonin reuptake inhibitors (SSRIs))
- if you take medicines for Parkinson's disease (levodopa, amantadine or orphenadrine)
- if you take medicines used for epilepsy (carbamazepine, phenytoin, phenobarbitone)
- if you take cyclophosphamide or ifosfamide, mainly used to treat cancer
- if you take ticlopidine or clopidogrel, mainly used to prevent stroke
- if you take some beta blockers
- if you take medicines for heart rhythm
- if you use nicotine patches to help you stop smoking.
- if you take ritonavir or efavirenz, medicines to treat HIV infection.

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

VOXRA XL may make other medicines less effective:

If you take digoxin for your heart, tell your doctor. Your doctor may consider adjusting the dose of digoxin.

Effect on urine tests:

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

VOXRA XL with food, drink and alcohol:

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

Pregnancy, breastfeeding and fertility:

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 taking VOXRA XL.

You should not take VOXRA XL when you are pregnant. Studies have reported an increase in the risk of birth defects, particularly heart defects, in babies whose mothers were taking VOXRA XL. If you are a woman of child-bearing potential, you should use reliable contraception.

Driving and using machinery:

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

3. How to take VOXRA XL:

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

Always take VOXRA XL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

How much to take:

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 VOXRA XL early in the morning.

Do not take VOXRA 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.

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, crush or split it – if you do, the medicine will be released into your body too quickly. If this happens you may be more likely to get side effects including seizures (fits).

Always take VOXRA XL exactly as your doctor has advised you. These are the usual doses, but your doctor's advice is personal to you. Check with your doctor or pharmacist if you are unsure.

How long to take it for:

Only you and your doctor can decide how long you should take VOXRA XL. It may take weeks or longer of treatment for you to see any improvement. Discuss your symptoms with your doctor regularly to decide how long you should be taking it. When you do start feeling better your doctor may advise you to keep taking VOXRA XL to prevent depression coming back. Do not stop taking VOXRA XL or reduce your dose without talking to your doctor first.

Sometimes VOXRA XL tablets have an unusual smell**.** This is normal: carry on taking the tablets as usual.

If you take more VOXRA XL than you should:

If you take too many tablets, you may increase the risk of a seizure (fit)**.**
Other serious effects may also happen. **Don't delay**. Ask your doctor what to do or contact your nearest hospital emergency department at once.

If you forget to take VOXRA XL:

If you miss a dose, wait and take your next tablet at the usual time. **Do not take a tablet to catch up** for the dose you forgot.

4. Possible side effects:

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

Seizures (fits):

People taking the maximum dose of VOXRA XL are at risk of a seizure (fit). The chance of this happening is higher if you take too much, if you take certain medicines in combination with VOXRA XL, or if you are at higher than usual risk of seizures (fits). If you are worried, talk to your doctor. If you have a fit, tell your doctor when you have recovered. Don't take any more tablets.

Allergic reactions:

Some people may get allergic reactions to VOXRA XL. These include:

- 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
- unusual wheezing or difficulty in breathing
- swollen eyelids, lips or tongue
- pains in muscles or joints
- collapse or blackout.

If you have any signs of an allergic reaction, contact a doctor at once. Don't take any more tablets. Allergic reactions can last a long time. If your doctor prescribes something to help with allergic symptoms, make sure you finish the course.

Lupus skin rash or worsening of lupus symptoms:

Lupus is an immune system disorder affecting the skin and other organs. Very rarely (up to 1 in 10,000) people may experience lupus skin rash or worsening of lupus symptoms while taking VOXRA XL. Symptoms include:

- lupus flares
- skin rash or lesions (particularly on sun-exposed areas)

➔ **If you experience lupus skin rash or worsening of lupus symptoms contact your doctor straight away, as it might be necessary to stop the treatment.**

Other side effects:

Frequent side effects: these may affect more than one in 10 people

- Difficulty in sleeping. Make sure you take VOXRA XL in the morning.
- Headache
- Dry mouth
- Feeling sick, vomiting

• Fever, dizziness, itching, sweating and skin rash (sometimes due to an allergic reaction)

• Shakiness, tremor, weakness, tiredness, chest pain

• Feeling anxious or agitated

• Tummy pain or other upsets (constipation), changes in the taste of food, loss of appetite (anorexia)

• Increase in blood pressure sometimes severe, flushing

• Ringing in the ears, visual disturbances.

Less frequent side effects may affect up to one in 100 people

• Feeling depressed (see also section 2‘Take special care with VOXRA XL’, under ‘Thoughts of suicide and worsening of your depression’)

• Feeling confused

• Difficulty concentrating

• Raised heart rate

• Weight loss

• Seizures

• Yellowing of skin or the whites of your eyes (jaundice) which may be caused by raised liver enzymes, hepatitis

• Palpitations, fainting

• Twitching, muscle stiffness, uncontrolled movements, problems with walking or coordination

•Stuttering

• Feeling restless, irritable, hostile, aggressive, feeling of panic (panic attack), strange dreams, tingling or numbness, loss of memory

• Severe allergic reactions; rash together with joint and muscle pains

• Changes in blood sugar levels

• Urinating more or less than usual

- Urinary incontinence (involuntary urination, leakage of urine)
- Decrease in blood sodium (hyponatraemia)
- Severe skin rashes that may affect the mouth and other parts of the body and can be life threatening
- Lupus skin rash or worsening of lupus symptoms (see the beginning of this section)
- Rash with pus filled pimples/blisters (*acute generalised exanthematous pustulosis*)
- Worsening of psoriasis (thickened patches of red skin)
- Feeling unreal or strange (depersonalisation); seeing or hearing things that are not there (hallucinations); sensing or believing things that are not true (delusions); severe suspiciousness (paranoia).

Talk about any troublesome side effects with your doctor or pharmacist. If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Thoughts of suicide or worsening of your condition:

If you are depressed, you can sometimes have thoughts of harming or killing yourself. These thoughts may be increased when first starting antidepressants. These medicines can take time to work - usually about two weeks, but sometimes longer (see also section 2).

Children under 18 years of age:

VOXRA XL should not be used to treat children under 18 years of age. There is an increased risk of suicidal thoughts and behaviour when children under 18 years of age are treated with antidepressants.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form",** found on-line 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 VOXRA XL

5. How to store VOXRA XL:

Keep out of the reach and sight of children.

Store at or below 25 °C. Keep well closed.

Store it in the original pack, out of direct sunlight.

Do not use after the expiry date stamped on the outer pack.

If you have any VOXRA XL left over once you've finished treatment, take them back to the pharmacist. Do not throw VOXRA XL in water or household waste.

6. Contents of the pack and other information:

What VOXRA XL contains:

Each VOXRA XL 150 tablet contains 150 mg of bupropion hydrochloride.

Each VOXRA XL 300 tablet contains 300 mg of bupropion hydrochloride.

The other ingredients are:

Tablet core: Polyvinyl alcohol, glyceryl behenate

Film-coat: Ethylcellulose 100, povidone, polyethylene glycol 1450, methacrylic acid copolymer dispersion (Eudragit L30 D-55), silicon dioxide, triethyl citrate, edible black ink (for printing) (containing Shellac glaze, isopropyl alcohol, Iron Oxide black, n-butyl alcohol, propylene glycol and ammonium hydroxide).

What VOXRA XL looks like and contents of the pack:

VOXRA XL 150 mg: Creamy white to pale yellow, round tablet, imprinted with 'GS 5FV 150' in black ink on one side and the other side plain**.**

VOXRA XL 300 mg: Creamy white to pale yellow, round tablet, imprinted with ‘GS 5YZ 300’ in black ink on one side and the other side plain.

White opaque plastic HDPE bottles with white polypropylene plastic child-resistance closures, containing 30 tablets.

Holder of certificate of registration:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

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